

Milan February 7th 2017

# **Biological aspects of TransOsseous**

# **Claudio Chillemi**



stituto

Chirurgico Ortopedico

Traumatologico

Latina - Italy



# Tendon tear

### Tendon – to - tendon









### **Tendon tear**



**Surgical goal** 

# Approximation and maintainance of contact between the tendon stumps





# **Surgical goal**

# Approximation and maintainance of contact between the tendon stumps



#### to activate...



### The cascade: 3 overlapping phases

- 1. Inflammation (0 7 days)
- 2. Proliferative (5 25 days)
- 3. Modelling (6 weeks)



Fibrillogenesis in tendon healing: an experimental study. Gigante A, Specchia N, Rapali S, Ventura A, de Palma L. Boll Soc Ital Biol Sper. 1996 Jul-Aug;72(7-8):203-10



## **Tissue injury**

degradation products of ECM

**Neutrophils influx** 

Inflammation Inflammation **Monocytes/Macrophage** accumulation

> vasoactive mediators

chemotactic factors

growth enzymes factors

## High synthesis of collagen type III



High water content

**High GAG concentrations** 





The healed tendon remains hypercellular

The  $\ensuremath{\ensuremath{\mathcal{O}}}$  of collagen fibrils is thinner

**Decrease cellularity** 

Nodeline Lower collagen and GAG synthesis



The healing tissue is resized and reshaped

# Rotator cuff tendon tear

# **Tendon – to – bone junction**









# **Surgical goal**

#### 1. Reattachment of the tendon to bone at its junction





# **Surgical goal**

### 2. Formation of the *enthesis* at the site of repair

- 1. Tendon
- 2. Uncalcified Cartilage
- **3** Calcified Cartilage
- 4. Bone





- anteriorly and posteriorly than in the mid portion

# - at the firmly held points of the repair (sutures)



Histological evaluation of repair of the rotator cuff in a primate model

D. H. SONNÅBEND, C. R. HOWLETT, A. A. YOUNG



VOL. 92-B, No. 4, APRIL 2010





#### Source of cells during the proliferative phase



Histological evaluation of repair of the rotator cuff in a primate model

D. H. SONNABEND, C. R. HOWLETT, A. A. YOUNG



# **Bursal contribution**



The features seen in our study population seem to give to bursal tissue a prominent role in the healing process after RCT, in particular, if one is facing large RCTs in elderly patients.

Rotator cuff re-tear or non-healing: histopathological aspects and predictive factors

C. Chillemi · V. Petrozza · L. Garro · B. Sardella ·

R. Diotallevi · A. Ferrara · A. Gigante · C. Di Cristofano ·

A. Castagna · C. Della Rocca

Knee Surg Sports Traumatol Arthrosc (2011) 19:1588-1596





from the GT



# source of cells and vessels

most prominent

The biology of rotator cuff healing

M.-A. Zumstein<sup>a,\*</sup>, A. Lädermann<sup>b</sup>, S. Raniga<sup>a</sup>, M.-O. Schär<sup>a</sup>

Orthopaedics & Traumatology: Surgery & Research xox (2016).







#### Rotator Cuff Healing and the Bone Marrow "Crimson Duvet" From Clinical Observations to Science

Stephen J. Snyder, MD and Joseph Burns, MD

Techniques in Shoulder & Elbow Surgery • Volume 10, Number 4, December 2009



#### DEFINITION OF CRIMSON DUVET

The term, "Crimson duvet" describes a reddish purple (crimson) colored clot that issues forth from small "bone marrow vents" punctured in the cortex of the greater tuberosity during rotator cuff repair surgery.<sup>1,2</sup> The perforations must



(duvet). This "super clot" is known to contain a rich cache of mesenchymal stem cells (MSCs), platelets with their growth factors and vascular elements, and vascular access channels, all of which will contribute to cuff healing.





# **Optimal preparation of the bony side of the lesion**

#### exposition and bleeding of the cancellous bone







# **Optimal preparation of the bony side of the lesion**

exposition and bleeding of the cancellous bone



NO risk of anchor pull-out



# Stable and solid fixation of the tendon – to - bone

#### with different suture configurations



Arthroscopic transosseous (anchorless) rotator cuff repair

Raffaele Garofalo · Alessandro Castagna · Mario Borroni · Sumant G. Krishnan

Knee Surg Sports Traumatol Arthrosc (2012) 20:1031-1035



# Stable and solid fixation of the tendon – to - bone

#### with different suture configurations



A Laboratory Comparison of a New Arthroscopic Transosseous Rotator Cuff Repair to a Double Row Transosseous Equivalent Rotator Cuff Repair Using Suture Anchors

Frederick J. Kummer, Ph.D., Michael Hahn, M.D., Michael Day, B.S., M.Phil., Robert J. Meislin, M.D., and Laith M. Jazrawi, M.D.

Bulletin of the Hospital for Joint Diseases 2013;71(2):128-31



# Stable and solid fixation of the tendon – to - bone

#### with different suture configurations



Advantages of Arthroscopic Transosseous Suture Repair of the Rotator Cuff without the Use of Anchors

Shigehito Kuroda MD, Noriyuki Ishige MD, Motohiko Mikasa MD

Clin Orthop Relat Res (2013) 471:3514-3522



# Stable and solid fixation of the tendon – to - bone

#### with different suture configurations



Midterm clinical outcomes following arthroscopic transosseous rotator cuff repair.

Flanagin BA, Garofalo R, Lo EY, Feher L, Castagna A, Qin H, Krishnan SG

Int J Shoulder Surg 2016 Jan-Mar;10(1):3-9.



# Stable and solid fixation of the tendon – to - bone

#### with different suture configurations



Arthroscopic transosseous rotator cuff repair: the eight-shape technique

Claudio Chillemi<sup>1</sup> · Matteo Mantovani<sup>2</sup> · Marcello Osimani<sup>3</sup> · Alessandro Castagna<sup>4</sup>

Eur J Orthop Surg Traumatol 2017



# Stable and solid fixation of the tendon – to - bone

#### with different suture configurations



#### Arthroscopic Trans-Osseous Rotator Cuff repair

Claudio Chillemi and Matteo Mantovani

MLT Journal 2017



# No any device interposition (anchors) between tendon – to - bone





Take home message

# **Tendon – to – bone healing**



- $\rightarrow$  from the bone
- → from the bursa







# Rotator cuff tendon tear



# c\_chillemi@libero.it



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# TRANSOSSEOUS



A. xxxx xxxx, Italy





# Introduction and rationale Why transosseous from the past to the future When believes are passed by substantial results Clinical outcome, experience of early adopters

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# Rotator Cuff Repair Closing the Defect

• Open Surgery









#### **Introduction and rationale**

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# Rotator Cuff Repair: Closing the Defect

• Arthroscopic Surgery











#### **Introduction and rationale**





#### ...rotator cuff repair approaches evolved from a single medial row to configurations that mimic the transosseous effect (double row and suture bridge) up to the more recent transosseous repair







#### **Double Row RepairR**

From a mechanical stand point how DR works?Why medial failure?

#### **Introduction and rationale**



# Sharc-FT + Taylor stitcher







#### Why transosseous from the past to the future

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<u>**Taylor**</u> is a steady cortical engaging suture platform able to load several high strength suture because of its stability into the bone. This system makes use of a transosseous tunnel avoiding a direct contact between bone and suture and exceeding the previous limitations of transosseous technique.



#### Why transosseous from the past to the future
# **Current "golden standard" solutions**

The current arthroscopic standard solutions for shoulder surgery are:

#### Anchors

#### Transosseous sutures

- **Pros:** 
  - Clinical outcome:
    - Healing
  - Reduced "direct" cost (no ٠ implanted device).
- Cons:
  - Invasive:
    - "open" or "mini open" surgery.
  - Complex:
    - Steep and long learning curve for the surgeon;
  - **Clinical issues:** 
    - Weak interface suture/bone: high risk of bone (or tendon) mechanical damage.
  - Increased "indirect" cost
    - Longer hospitalisation.

#### Sharc-FT

•

- Combining the advantages of the existing solutions, avoiding the issues:
  - Best clinical outcome: •
    - Healing
    - No pull out
    - No bone damage
  - Mini invasive surgery: •
    - Reduced N°of holes
  - Predictable cost per • procedure
    - Typically lower than anchors.

### transosseous from the past to the future

- **Pros:** 
  - Established solution:
    - Well known by surgeons;
    - Established results and follow up;
  - Mini invasive surgery; ٠

#### Cons:

- **Clinical issues:** 
  - Low pull out threshold in poor bone quality;
  - Migration documented (over 10% in case of major damages) with resulting shoulder damage;
- (Uncertain) procedure cost: •
  - Very often the procedures requires several anchors (high cost).
- Today's market leading ٠ solution (approx. 90% market share) with substantial issues.



# **The Original Motivation**

#### The Incidence of Early Metallic Suture Anchor Pullout After Arthroscopic Rotator Cuff Repair

Eric C. Benson, M.D., Joy C. MacDermid, B.Sc.P.T., M.Sc., Ph.D., Darren S. Drosdowech, M.D., F.R.C.S.C., and George S. Athwal, M.D., F.R.C.S.C.







FIGURE 1. (A) Anteroposterior (AP) portable radiograph immeditately protoperatively showing repair of a 1-cm suprapriatus tear in a 77-year-oft man. (B) Anteroposterior shoulder radiograph 2 weeks postoperatively showing early metallic suture anchor pullout. (C) introperative arthrocopic image showing the pulle-out anchor still sutured to the fluide cut repair.

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### REVISION ROTATOR CUFF REPAIR: Factors Influencing Results

BY MLADEN DJURASOVIC, MD, GUIDO MARRA, MD, JULIAN S. ARROYO, MD, ROGER G. POLLOCK, MD, EVAN L. FLATOW, MD, AND LOUIS U. BIGLIANI, MD

Investigation performed at the Department of Orthopaedic Surgery, New York Presbyterian Hospital—Columbia Presbyterian Medical Center, New York, NY

**Conclusions:** The results of revision rotator cuff repair are inferior to those of primary repair. While pain relief can be reliably achieved in most patients, the functional results are improved principally in patients with an intact deltoid origin, good-quality rotator cuff tissue, preoperative elevation above the horizontal, and only one prior procedure.

tuberosity. **Conclusions:** There is a minimal risk of suture anchor pullout in small- to medium-sized tears; however, this risk increases with larger tear sizes. We recommend routine radiographic follow-up after use of metallic anchors to ensure identification of early failure by anchor pullout. **Level of Evidence:** Level III, prognostic case series.

#### CONCLUSIONS

Complications of Metallic Suture Anchors in Shoulder Surgery: A Report of 8 Cases

T. Kenneth Kaar, M.D., Robert C. Schenck, Jr., M.D., Michael A. Wirth, M.D., and Charles A. Rockwood, Jr., M.D.

surgery. **Conclusions:** The use of metallic suture anchors about the shoulder is commonplace and useful, but, as with other hardware used about the shoulder, there are significant risks if the anchors are improperly placed or if the index procedure fails. **Key Words:** Complications—Suture—Anchor—Metallic—Shoulder.

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# **The Original Motivation**







## From a biomechanical stand point

transosseous repair has shown over time many advantages and some limits ...

- •Large Foot print coverage
- •Uniform pressure distribution and greater stability at bone tendon interface
- •More even stress distribution (elimination of spikes)
- •Good resistance to gap formation with high load level
- •Transosseous tunnel stability



#### WIDER FOOT-PRINT COVERAGE

 APRELEVA 2002 : in tears 2 cm large comparing single stitches in <u>T</u> vs <u>2</u> mattresses in a T. vs <u>2</u> anchors single stitches vs <u>2</u> anchors mattress stitches

20% larger foot print in transosseous (T) repair

**MEIER 2006** : tears 2 cm large comparing 2 simple stitches in T. vs 2 anchors and simple stitches

25% larger foot print in transosseous (T) repair

TUOHETI 2005 : tears 2 cm large comparing 2 Mason Allen vs 2 anchors with single stitches

31% larger foot print in transosseous (T) repair

#### PRESSURE AT BONE-TENDON INTERFACE

• TUOHETI A.J.S.M.

### THE AVERAGE PRESSURE IS 18-20% BIGGER IN ANCHOR REPAIR

**SPIKES PRESENCE** IS THE AREAS AROUND THE ANCHORS AND VERY LOW IN BETWEEN THE ROWS

#### GREATER HOMOGENEITY IN A T REPAIR IN TERM OF PRESSURE VALUES

#### 41

#### FATIGUE RESISTANCE

(75 N FOR 50 CYCLES THEN 100 N FOR 50 CYCLES THEN PROGRESSIVE INCREASE OF 25N UP TO FAILURE )

#### PIETSCHMAN

3 ANCHORS VS DOBLE TRANSOSSEUS REPAIR IN OSTEOPENIC AND HARD BONE

RESULTS

NO SIGNIFICANT DIFFERENCE IN HARD BONE WITH BOTH APPROACHES

OSTEOPENIC BONE REDUCTION OF UTS FROM 190-200N TO 120-150 <u>N</u>, ON AVERARE TRANSOSSEOUS RESULT IS INFERIOR TO ANCHORS AND THE FAILURE MODE IS DIFFERENT

#### 100% TUNNELS FAILURE IN T.

70% PULL-OUT WITH ANCHORS

#### Tendon to Bone Interface Mobility

AHMAD C.S. A.J.S.M.

The relative movement between tendon and bone IS SIGNIFICANTLY INFERIOR IN A TRANSOSSEOUS (T) APPROACH IF COMPARED TO ANCHORS REPAIR

- TOCCI JSES 2008
- LARGE LESIONS TESTED WITH 2-3 MASON.ALLEN VS ANCHORS AT LOW LOAD LEVEL FOR 4000 CYCLES AND AT HIGH LOAD LEVEL FOR 2000 CYCLES

NO SIGNIFICANT DIFFERENCE AT LOW LOAD LEVEL

#### GAP FORMATION IS BIGGER AT HIGH LOAD LEVEL WITH ANCHORS

#### MAXIMUM LOAD AT FAILURE CRAFT JSES 1996

2 MATTRESS STITCHES IN A T. APPROACH TESTED AT 35 MM/SEC (FAST) VERSUS 2 ANCHORS WITH MATTRESS STITCHES 228 N. VS 180-250 DEPENDING ON ANCHORS MODEL

#### BURKHEAD CLIN ORTHOP REL RESEARCH 2007

<u>3</u> SUT. MATTRESS T. VERSUS <u>3</u> ANCHORS TESTED AT <u>6 MM</u>/MIN (SLOW) NO SIGNIFICANT DIFFERENCE

#### NO SIGNIFICANT DIFFERENCES BETWEEN T. AND ANCHORS BOTH AT SLOW AND FAST SPEED TEST

#### FAILURE MODE

- BURKHART : with T. 40% tunnel failures, with anchors 90% of failure at the tendon interface
- MEIER : in T. with simple stitches 75% tunnel failures, with anchors repair and simple stitches (SS) 55% suture failure, 45% at tendon level
- GORADIA : 78% failure at tunnel level in T. and 75% at tendon level with anchors
- WALTRIP : T. with Mason Allen 100% tunnel failure, with resorbable anchors and SS 100% anchors pull out !

#### **Conclusion:**

in a T. approach the failure occurred at the tunnel level with anchors occurred at tendon level



# SUMMARY

 The anchors based repair evolved from single medial row to approaches that mimic the transosseous effect (Transosseous equivalent or suture bridge)

The transosseous repair shows some advantages
pressure distribution, absence of spikes, greater stability
at tendon-bone interface, fatigue resistance at high load
level, foot print coverage

The most evident limit is at the tunnel level: tunnel failure at high load with osteopenic bone



## Why transosseous from the past to the future

### Anchors

### Transosseous

	Contact area (tendon – bone)	
	Stress distribution	
	Gap formation	
	Hematic supply	
	Hardware presence in the foot print	
	Pull-out and intra articular migration risk	Not possible
	What in case of poor bone quality	
tendon	Failure	tunnel



#### MECHANICAL STRENGTH OF REPAIRS OF THE ROTATOR CUFF

CHRISTIAN GERBER, ALBERTO G. SCHNEEBERGER, MARTIN BECK, URS SCHLEGEL

From the Hôpital Cantonal, Fribourg, the University of Berne and the AO Research Institute, Davos, Switzerland



Level V Evidence Article With Video Illustration

The Evolution of Suture Anchors in Arthroscopic Rotator Cuff Repair

Patrick J. Denard, M.D., and Stephen S. Burkhart, M.D.

Review Article Clinics in Orthopedic Surgery 2013;5:89-97 • http://dx.doi.org/10.4055/cios.2013.5.2.89

#### Current Biomechanical Concepts for Rotator Cuff Repair

Thay Q Lee, PhD

Orthopaedic Biomechanics Laboratory, Long Beach VA Healthcare System, Long Beach & Department of Orthopaedic Surgery, University of California, Irvine, CA, USA



- initial stiffness and strength of the repair (UTS)
- **G** gap formation resistance
- sliding stability in intra-extra rotation in the immediate post op
- maximization of the footprint original coverage
- optimization of the contact pressure at the interface tendon-bone

Which are the factors affecting the transosseous approach performance:

- ✓ Depth of the lateral tunnel
- ✓ Tunnel shape
- Avoid direct inpingement sutures/bone in sharp corners
- ✓ Distribute pressure at the interface (avoid peaks)
- Load sharing construct (by increasing the sutures number and bridging the construct)
   When believes are surpassed by concrete results

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# **Depth of the lateral tunnel...**2 cm seems to be an optimal compromise





**Fig. 12** A postoperative MR image shows the average distance from the superior border of the greater tuberosity to the insertion point of the K-wires (K) as 17.7 mm. The distance between the superior border of the greater tuberosity and the axillary nerve (A) has been reported as 35 to 45.6 mm.

Clin Orthop Relat Res (2013) 471:3514–3522 DOI 10.1007/s11999-013-3148-7 Clinical Orthopaedics and Related Research® A Publication of The Association of Bone and Joint Surgeons®

MULTIMEDIA ARTICLE

#### Advantages of Arthroscopic Transosseous Suture Repair of the Rotator Cuff without the Use of Anchors

Shigehito Kuroda MD, Noriyuki Ishige MD, Motohiko Mikasa MD

Arthroscopy. 1997 Oct;13(5):600-5.

#### Morphology of the axillary nerve in an anteroinferior shoulder arthroscopy portal.

Nassar JA<sup>1</sup>, Wirth MA, Burkhart SS, Schenck RC Jr.

The distance from the lateral tuberosity is a parameter that is of extreme importance to have a more consistent bone quality. At around 2 cm from the lateral margin of the tuberosity it has been demonstrated the bone density is frequently better than in the area immediately close to the tuberosity and the area has been proven to be safe from damaging the axillary nerve. In our experience, by lowering 1 cm more from the lateral margin of the tuberosity (reaching a depth of 3 cm) we are still in a safe area (as reported previously) and the lateral cortex is becoming significantly more consistent but having a direct view of this area in an arthroscopic approach could be tricky and this can directly impact over operative time required. In conclusion, the variability of the bone density is a critical issue that can significantly impact over the final repair performance (sometime in a catastrophic way making the repair inconsistent for an excessive gap formation in the early period).

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# **Tunnel shape...**rounded smooth tunnel and bringing

### the sutures close to the exit point

Clin Orthop Relat Res (2013) 471:3514–3522 DOI 10.1007/s11999-013-3148-7 Clinical Orthopaedics and Related Research® A Publication of The Association of Bone and Joint Surgeons®

MULTIMEDIA ARTICLE

Advantages of Arthroscopic Transosseous Suture Repair of the Rotator Cuff without the Use of Anchors

Shigehito Kuroda MD, Noriyuki Ishige MD, Motohiko Mikasa MD

Fig. 1.A-B: (A) The aiming tip of the drill guide passing through the anterolateral portal was placed on the medial edge of the footprint and three K-wires with perforated tips were inserted through the inferior margin of the greater tuberosity. (B) The rotator cuff stump was pulled laterally, and the K-wires were threaded through the rotator cuff and skin posterior to the acromicolavicular joint.



Springer

### Biomechanical Evaluation of Transosseous Rotator Cuff Repair

#### **Do Anchors Really Matter?**

Michael J. Salata,<sup>\*</sup> MD, Seth L. Sherman,<sup>†</sup> MD, Emery C. Lin,<sup>‡</sup> MD, Robert A. Sershon,<sup>§</sup> BS, Aman Gupta,<sup>§</sup> PhD, Elizabeth Shewman,<sup>§</sup> MS, Vincent M. Wang,<sup>§</sup> PhD, Brian J. Cole,<sup>§</sup> MD, Anthony A. Romeo,<sup>§</sup> MD, and Nikhil N. Verma,<sup>§||</sup> MD *Investigation performed at the Rush University Medical Center, Chicago, Illinois* 

hen believes are surpassed by concrete





**Figure 6.** Maximum load to failure with standard deviation. \*The transosseous-equivalent (TOE) group exhibited a statistically greater maximum load than the transosseous (TO), ArthroTunneler (AT), and ArthroTunneler X-box (ATX) groups.

# Avoid direct sutures/bone inpingement in sharp corners



Gap formation in a transosseous rotator cuff repair as a function of bone quality



<sup>a</sup> NCS Lab, Carpi, Italy

<sup>b</sup> Orthopedic and Traumatology Department, University of Modena, Modena, Italy

<sup>c</sup> Unit of Shoulder and Elbow Surgery, D. Cervesi Hospital, Cattolica, Italy

<sup>d</sup> Orthopedic and Traumatology Department, University of Parma, Parma, Italy





CrossMark



## **Introduction**

✓ Distribute pressure at the interface (avoid peaks)...evenly distributed pressure is beneficial preventing muyual slip between tendon and bone

# Stress Distribution in the Supraspinatus Tendon After Tendon Repair

#### **Suture Anchors Versus Transosseous Suture Fixation**

Hirotaka Sano,\*<sup>†</sup> MD, Takeshi Yamashita,<sup>‡</sup> MSc, Ikuko Wakabayashi,<sup>§</sup> MD, and Eiji Itoi,<sup>†</sup> MD From the <sup>†</sup>Department of Orthopaedic Surgery, Tohoku University School of Medicine, Sendai, Japan, the <sup>‡</sup>Department of Materials Processing, Graduate School of Engineering, Tohoku University, Sendai, Japan, and the <sup>§</sup>Department of Orthopaedic Surgery, Akitaken Taiheiryouikuen Hospital for Disabled Children, Akita, Japan

**Results:** In the single-row model, the stress appeared from the site of the anchor and extended into the proximal tendon. The highest stress concentration was observed on the bursal surface of the tendon. The double-row model showed a similar pattern to the single-row model except that the stress concentration was observed only around the medial anchor. In the transosseous model, the stress appeared from the attachment site to a bony trough, which extended proximally into the tendon substance. No significant stress concentration was observed inside the tendon.

Conclusion: Both single-row and double-row fixations showed higher stress concentration inside the tendon than did transosseous suture fixation.

**Clinical Relevance:** A high stress concentration might be a cause of the rerupture often observed after arthroscopic cuff repair using suture anchors.

# Load sharing construct (by increasing the sutures number and bridging the construct)...bridging and linking sutures permit an even distribution of the acting load avoiding local stress peaks

Copyright © 2012 by The Journal of Bone and Joint Surgery, Incorporated

### Suture Number Determines Strength of Rotator Cuff Repair

Patrick W. Jost, MD, M. Michael Khair, MD, Dan X. Chen, MS, Timothy M. Wright, PhD, Anne M. Kelly, MD, and Scott A. Rodeo, MD

Investigation performed at the Sports Medicine and Shoulder Service, Hospital for Special Surgery, New York, NY

**Conclusions:** In an ovine rotator cuff tendon repair model, increasing the number of sutures decreased cyclic gap formation and increased load to failure. Single and double-row repairs are biomechanically equivalent when the number of sutures is kept constant.

Clinical Relevance: The results of this study support the use of greater numbers of sutures in rotator cuff repair and disagree with the assertion that double-row repairs are biomechanically superior to single-row repairs.

128 Bulletin of the Hospital for Joint Diseases 2013;71(2):128-31

A Laboratory Comparison of a New Arthroscopic Transosseous Rotator Cuff Repair to a Double Row Transosseous Equivalent Rotator Cuff Repair Using Suture Anchors

Frederick J. Kummer, Ph.D., Michael Hahn, M.D., Michael Day, B.S., M.Phil., Robert J. Meislin, M.D., and Laith M. Jazrawi, M.D.

Discussion: Biomechanical testing suggests that arthroscopic, transosseous rotator cuff repair using a Xbox suture configuration is similar in strength and stability to an arthroscopic transosseous equivalent suture-bridge repair. Both techniques demonstrated difficulty in maintaining the lateral position of the tendon.



# **Biomechanical rationale:**

• Sutures isolated from bone (bone cut eliminated)





Displacement (mm)

### Construct independent by bone quality





High static and dynamic performance (gap formation is very low compared to currently used techniques)



The static pull out performance is very high (even if the different working conditions don't require this).

 High static and dynamic performance (gap formation is very low compared to currently used techniques)

#### **Closed anchors vs 4 anchors**



Sharc-ft samples		Ti Anchors 5.0mm samples	
Mean (N)	STD Dev. (N)	Mean (N)	STD Dev. (N)
315.8	11.5	215.5	16.0



High static and dynamic performance (gap formation is very low compared to currently used techniques)



Gap reduction in a dynamic set up compared to double row techniques (massive lesion).



## When believes are surpassed by concrete results Large foot print area

#### Mechanical environment of the supraspinatus tendon: A two-dimensional finite element model analysis

J Orthop Sci (2008) 13:348–353 DOI 10.1007/s00776-008-1240-8 JOURNAL OF JOURNAL OF ORTHOPAEDIC SCIENCE The Japanese Orthoppaedic Association

Original article

#### Mechanical environment of the supraspinatus tendon: three-dimensional finite element model analysis

Nobutoshi Seki<sup>1</sup>, Elii Itol<sup>2</sup>, Yotsugi Shibuya<sup>3</sup>, Ikuko Wakabayashi<sup>4</sup>, Hirotaka Sano<sup>2</sup>, Ryuji Sashi<sup>5</sup>, Hiroshi Minagawa<sup>1</sup>, Nobuyuki Yamamoto<sup>1</sup>, Hidekazu Abe<sup>1</sup>, Kazuma Kikuchi<sup>1</sup>, Kyoji Okada<sup>1</sup>, and Yoichi Shimada<sup>1</sup>

<sup>1</sup>Division of Orthopedic Surgery, Department of Neuro and Locomotor Science, Akita University School of Medicine, Akita, Japan Department of Orthopaedic Surgery, Tohoku University Graduate School of Medicine, Sendai, Japan <sup>3</sup>Faculty of Engineering and Resources Science, Department of Mechanical Engineering, Akita University, Akita, Japan Department of Orthopaedic Surgery, Taiheiryoikuen, Akita, Japan

<sup>5</sup>Department of Radiology, Akita University School of Medicine, Akita, Japan

nee Surg Sports Traumatol Arthrosc OI 10.1007/s00167-012-2008-4

SHOULDER

### Nonlinear stress analysis of the supraspinatus tendon sing three-dimensional finite element analysis

tsushi Inoue • Etsuo Chosa • Keisuke Goto • aoya Tajima

# Stress Distribution in the Supraspinatus Tendon After Tendon Repair

#### Suture Anchors Versus Transosseous Suture Fixation

Hirotaka Sano,<sup>\*†</sup> MD, Takeshi Yamashita,<sup>‡</sup> MSc, Ikuko Wakabayashi,<sup>§</sup> MD, and Eiji Itoi,<sup>†</sup> MD From the <sup>†</sup>Department of Orthopaedic Surgery, Tohoku University School of Medicine, Sendai, Japan, the <sup>†</sup>Department of Materials Processing, Graduate School of Engineering, Tohoku University, Sendai, Japan, and the <sup>§</sup>Department of Orthopaedic Surgery, Akitaken Taiheiryouikuen Hospital for Disabled Children, Akita, Japan

Stress distribution in the supraspinatus tendon with partial-thickness tears: An analysis using two-dimensional finite element model



and Eiji Itoi, MD,<sup>b</sup> Sendai and Akita, Japan



			5,000 13,010
	Repair method	Repair Area	Contact area with a positive pressure
		(mm²)	(mm²)
eceived: 8 August 2011/Ac	Transosseous with a device in the tunnel	125	45,4
Springer-verlag 2012	Transosseous Equivalent (4 anchors, 2 screwed	103	42
	and 2 impacted laterally)	eous Equivalent (4 anchors, 2 screwed 103 42 acted laterally)	
	Single Row	35	15,9
	Double Row	87	26,8

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- Which is the connection between higher biomechanical properties and healing process?

- Why is important to keep a high stability with every bone condition?





Tendon-healing to cortical bone compared with healing to a cancellous trough. A biomechanical and histological evaluation in goats.

P St Pierre ; E J Olson ; J J Elliott ; K C O'Hair ; L A McKinney ; J Ryan J Bone Joint Surg Am, 1995 Dec;77(12):1858-1866

0363-5465/99/2727-0476\$02.00/0 THE AMERICAN JOURNAL OF SPORTS MEDICINE, Vol. 27, No. 4 © 1999 American Orthopaedic Society for Sports Medicine

#### Use of Recombinant Human Bone Morphogenetic Protein-2 to Enhance Tendon Healing in a Bone Tunnel\*

Scott A. Rodeo,†‡ MD, Katsunori Suzuki,† MD, Xiang-hua Deng,† MD, John Wozney,§ PhD, and Russell F. Warren,† MD J Bone Joint Surg Am. 1999 Sep;81(9):1281-90.

#### Experimental rotator cuff repair. A preliminary study.

Gerber C<sup>1</sup>, Schneeberger AG, Perren SM, Nyffeler RW.

#### Tendon-Bone Interface Motion in Transosseous Suture and Suture Anchor Rotator Cuff Repair Techniques

Christopher S. Ahmad,\* MD, Andrew M. Stewart, MD, Rolando Izquierdo, MD, and Louis U. Bigliani, MD From the Center for Shoulder, Elbow, and Sports Medicine, Department of Orthopaedic Surgery, Columbia University, New York, New York

there are some animal models that can be used as a link between mechanical properties and repair integrity after a period of healing

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### CURRENT CONCEPTS REVIEW Augmentation of Tendon-to-Bone Healing

Kivanc Atesok, MD, MSc, Freddie H. Fu, MD, DSc, DPs, Megan R. Wolf, BS, Mitsuo Ochi, MD, PhD, Laith M. Jazrawi, MD, M. Nedim Doral, MD, James H. Lubowitz, MD, and Scott A. Rodeo, MD

Investigation performed at the Sports Medicine and Shoulder Service, Hospital for Special Surgery, New York, NY; Center for Musculoskeletal Care, NYU Hospital for Joint Diseases, New York, NY; the Department of Orthopaedic Surgery, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania; the Department of Orthopaedic Surgery, Graduate School of Biomedica Sciences, Hiroshima University, Hiroshima, Japan; the Department of Orthopaedics and Traumatology, Hacettepe University School of Medicine, Ankara, Turkey; and Taos Orthopaedic Institute, Taos, New Mexico



### Ability to aggressively remove the cortical Bone – Stimulate Blood Flow





### **Tunnel effect**

J Shoulder Elbow Surg (2014) 23, 620-627



Journal of Shoulder and Elbow Surgery www.elsevier.com/locate/ymse

# Surface-holding repair: an original arthroscopic rotator cuff repair technique

Noboru Taniguchi, MD<sup>a,b,\*</sup>, Naoki Suenaga, MD<sup>c</sup>, Naomi Oizumi, MD<sup>c</sup>, Naoki Miyoshi, MD<sup>d</sup>, Noriya Araki, PT<sup>e</sup>, Etsuo Chosa, MD<sup>a</sup>

In addition, cell-mediated tissue healing and regeneration might be expected in our technique. Mesenchymal stem cells derived from the bone marrow through the bone tunnel and drilled anchor holes have the potential to differentiate into tendon tissues.<sup>5</sup> Our contrast-enhanced ultrasonography analysis for the repaired cuff showed that the longitudinal blood flow in intratendinous tissue was augmented even at 3 months after rotator cuff repair.<sup>13</sup> Thus, our surgical procedures providing multiple bone tunnels and drilled anchor holes may facilitate the healing process of rotator cuff tissues by bone marrow–derived cells released from the humeral bone.







### **Improvement compared to classical transosseus (retrospective** study – 40 pts each group – 2012 SICSEG)



where a more freely requir, when mapping team were found, suggest instrumentations allow to realize multiple medial holes, 3-ionm in dameter, th any to obtain a more subside summer distribution. Seldon, when a rotator caff recommutant is needed, it is also possible to use two implanted de

CLINICAL EVALUATION OF TRADITIONAL TRANSOSSEOUS AND Sharc-FT ROTATOR CUFF REPAIR









#### UNIVERSITA' DEGLI STUDI DI PARMA

SCUOLA DI SPECIALIZZAZIONE IN ORTOPEDIA E TRAUMATOLOGIA

DIRETTORE: PROF. F. CECCARELLI

LA SUTURA TRANSOSSEA ARTROSCOPICA DELLA

CUFFIA DEI ROTATORI

Specializzando:

Dr. Leonardo Armillotta







# Materials & Methods

- September 2010 June 2013: 98 implanted devices (45 M 53 F)
- Average age: 63,6 years (41 77)
- Lesion type: 1,5-3,5 cm, SVSP + STSP
- 30 patients with an average follow up of 23,5 months
   (20 26)

Clinical evaluation: Constant-Murley score pre-op and at 3,6,12 and 24 months

- imaging evaluation
  - Rx post-op and after 1 y
  - RM at 6 months
- surgical technique:
  - 1 Sharc-FT<sup>®</sup> loaded with 3 sutures
  - sutures configurations SR o SB



RM



# Results

Constant score	Avg	Min	Max
pre-op	24.5	16	68
3 months	63.1	44	82
6 months	83.2	47	90
12 months	86.9	48	90
24 months	87.0	56	90

- RM at 6 months:
  - \* no device migration
  - no healing failure
  - no re-tear

## **Complications at 24 m**

2 Adhesive capsulite Suspected re-tear 1 clinical failure Clinical outcome, experience of early adopters

# **Clinical case... IMAGING**







### **Rx post-op**





Discussion

## 18 Months ...

Musculoskelet Surg (2013) 97 (Suppl 1):S57-S61 DOI 10.1007/s12306-013-0254-3

ORIGINAL ARTICLE

The rotator cuff tear repair with a new arthroscopic transosseous system: the Sharc-FT<sup>®</sup>



PRIMO FOLLOW UP PUBBLICATO

P. Baudi · E. Rasia Dani · G. Campochiaro · M. Rebuzzi · F. Serafini · F. Catani

## ... 33 Months

# Good/Excellent functional recovery with a good return to daily activities

none migration

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# CONCLUSION

## Adavantages:



- from a biological and biomechanical stand point is a gold standard technique
- Reproducible technique with good functional outcome
- good re-retear scorepossible functional improvement from the early post op







January 2013 - December 2013

## **27 pts** (14 females / 13 males)

Involved Side: 16 right / 11 left (Dominant side 18 pts)

Mean age 57,3 ys (range 42-74)



#### Data, results and opinions taken from Dr Petriccioli series

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## Summary: Disadvantages

- Medium Long learning curve
- Outcomes research needed
- Longer mean surgical time
- No cost advantage in small lesion

#### Summary: Advantages

- Trans-osseous RCR represents the gold standard
- Arhroscopic trans-osseous equivalent RCR is an
  - emerging technology
- · Recreate the original tendon foot-print
- No hardware migration in osteopenic bone
- Potential cost savings (avoid anchor use)
- · Useful in arthroscopic tuberosity reconstruction





- This transosseous approach can overtake the past limitations of the traditional approach providing a stable contruct, indipendent by bone quality
- Several independent groups have testified the good clinical outcome in severe conditions: large to massive tears, revision cases and severly osteopoenic bone
- □ There is a learning curve that can increase initially operative time; the approach is reproducible and gives sevral degree of freedom in the repair approach



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Karl Storz, 23/05/2013

## Sharc ft Shoulder Arthroscopic Repair Construct

## <u>Learn the lesson</u>

FAQ

## The compass instrumentation seems to be time consuming in respect to the current anchor procedure

Answer – After a short learning curve (3 to 5 cases) the time required with a normal lesion is comparable to that currently used while with a massive lesion it is more efficient

## Which is the stability of the device? What about possible migration?

Answer – The system was created for massive lesions in osteoporotic condition. The pull out performance is comparable to best in place while the way it works is completely different (the system is auto balanced and the active forces on the device are not directed in the extraction direction). Optimal performances are also guaranteed when in presence of very poor bone quality. The device is also placed extra articulation and the risk of impingement is null.



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mechanical comparison of different repair techniques in the rotator cuff repair

## How many cases have been done and which is the follow up?

Answer – we have directly monitored more than >1500 cases and the follow up of the first 40 cases is 50 months. No one Sharc has mobilized and the healing process was incredibly straight. Several publications are under the way and a randomized multicentric blind study started in January 2014

	by the use of a 3D finite element model		
Musculoskelet Surg (2013) 97 (Suppl 1):S57-S61 DOI 10.1007/s12306-013-0254-3	M. Mantovani		
ORIGINAL ARTICLE	- Background Contact pressure and contact area are between the most important mechanical factors studied to pri-	edict	
The rotator cuff tear repair with a new arthroscopic transosseous system: the Sharc-FT $^{\textcircled{P}}$	the effectiveness of a repair. The suture configurations can strongly affect these factors but are sele correlated.	dom	
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VUMEDI Specialties - Browse - Adult Recon - Foot & Ankle Hand & Wrist - Pediatric	A new arthroscopic transosseous cuff repair: the sharc-ft tech By Paolo Baudi Straces Shoulder & Elbow + Spine P		
S Taylor stitcher By Simone Bizzotto 21/dece	Panlo Bandi Michel Verdano Gabriek Campecharo Andrea Pelegrini Fablo Catani Franceso Cecerili With the support of Share Taking Boord		
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## Which is the main advantage of the implant?

Answer –The implant permits to create a very stable construct that maximize the foot print and the contact pressure between tendon and bone. The implant could also be considered a platform for sutures in the sense that several sutures could be loaded (as many as needed for the reparation) and the sutures configuration is completely free (several examples are also visible in the other document). We Answer the old transosseous technique problems avoiding the classical drawbacks (direct impingement between sutures and bone). We have also the inner sutures that work vertically avoiding the detachment tendon-bone and keeping a compression along the whole range of motion.

Unique in revision and in large to massive lesions in presence of osteoporotic bone





## How many Sharc shall be used?



Answer – in most cases (80%) 1 implants is more than enough and the construct stability is superior to techniques such as transosseous equivalent with 4 anchors.

## Could this technique be considered a transosseous equivalent?

Answer – this technique is a real transosseous because the inner (transosseous sutures) could be closed in a ring reproducing the optimal anatomical reconstruction.

## Which is the holes dimension?

Answer – 3 mm with the compass while 1,9 mm with Taylor Stitcher. We have one lateral hole and at least one in the greater tubercle. The instrumentation permits to have one entry hole and multiple exit holes to optimize the reconstruction





## Could this device be used in massive lesion?

Answer – The device was created for massive lesion. The biomechanical validation of the device was vs 4 anchors while greater majority of cases interested large to massive lesions providing an excellent clinical outcome.

## What about the axillary nerve and the instrumentation?

Answer- The instrumentation was created to avoid this problem and can be regulated to keep the entry hole as much proximal as one desires keeping in any case a consistent bone bridge that could avoid greater tubercle failures due to suture tension.

## What if in case we have a prominent acromion?

Answer – The Taylor Stitcher starts from lateral so acromion is not an issue while the compasso as the same inclination as anchors so nothing change from habits.







## Which kind of lesions can be treated?

Answer – Several types of lesions could be treated interesting one or more tendons and affecting supraspinatus, infraspinatus and subscapularis. From small to massive.

## Can the system be used in arthroscopic approach?

Answer – The approach was created to be completely arthroscopic but also works in open and mini open

## Shall this system be used in beach chair or in lateral positioning?

Answer – The system could be used in both approaches.

## Which is the greater tuberosity decortication effect?

Answer – Bleeding is a positive factor leading to a natural growth factor release. No synthetic materials in the foot print area.





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## Isn't the device dimension too big?

Answer – The sharc (and Elite as well) length is 16 mm like a traditional anchor and the overall weight is 2,7g (0,9 g Elite). The hardware reduction (compared to a traditional approach) in the humeral head is significant.

## Is the taylor strong enough to bore the cortical bone?

Answer – The conceived mechanism and the possibility of impacting the handle permit to bore very hard surfaces. Nitinol is very resistent to bending and no failure have never been experienced.

# <u>I'm good and quick with anchors, why shall I learn a new technique and face the learning curve?</u>

Answer – This device is superior from a biomechanical stand point but most importantantly offer the many advantages of transosseous overtaking the original weaknesses. This approach is unique in several cases: revision, massive lesions, osteoporotic bone.





## What if the user refuses to clean the lateral bursa?

Answer – This additional step is mandatory to have a clear view of the whole phases (at least in the learning curve period).

# With the Taylor stitcher I have to isert the targeting needle through the skin several time?

Answer – This is part of the training; once the 3D view is clear to the user the targeting needle may be even avoided.







## ArthroTunneller

- 1 entry 1 exit
- Single patient
- High cost
- It doesn't fit a cannula
- Small bone bridge





## Target

- Miniopen incision (large incision)
- All rotator cuff lesion
- They provide a tunnel augmentation



What about competitors? Which the main differences with



Arthrotunneler (Tornier)?



## CurvTek

- Single use
- Not known
- To be avoided in osteoporotic bone



One Surgeon. One Patient.







# Why the need of a new device in RCR?

# The reasons beyond the project:

- Solve the problem of poor bone quality <sup>(\*\*)</sup>
- Unique in revision
- Create an easy and reproducible way of performing a transosseous approach
- Creating a superior biomechanical construct
- Can we improve in case of massive lesion?

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- Additional sutures can be loaded (up to 5 sutures have been used on a single device)
- Additional sutures can be loaded in the device tail even intra operatively
- Suture bridge construct reproduced with a single device
- Real transosseous loop preventing weak interface bone-suture problems
- Flexible and fast approach that permits several configurations (platform for sutures)
- Unique in revision
- Unique in osteoporotic bone





Sharc-FT® NCS Lab Srl. Via Pola Esterna 4/12 - 41012 Carpi (MO) Italy Superior capsular reconstruction of the shoulder: the ABC (Arthroscopic Biceps Chillemi) technique

## Claudio Chillemi, Matteo Mantovani & Antonio Gigante

## European Journal of Orthopaedic Surgery & Traumatology

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**TECHNICAL NOTE • SHOULDER - ARTHROSCOPY** 



# Superior capsular reconstruction of the shoulder: the ABC (Arthroscopic Biceps Chillemi) technique

Claudio Chillemi<sup>1</sup> · Matteo Mantovani<sup>2</sup> · Antonio Gigante<sup>3</sup>

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#### Abstract

Superior capsular reconstruction (SCR) demonstrated its efficacy as a treatment option available in patients affected with irreparable posterosuperior rotator cuff tears without any signs of arthritis. Originally, the fascia lata autograft was fixed medially to the glenoid (with two or more anchors) and laterally to the greater tuberosity (with a compression double-row technique using four anchors or three transosseous tunnels). Additionally, side-to-side sutures were used to anteriorly and posteriorly connect the graft to the native residual rotator cuff tissue. However, the fascia lata as an autograft has a disadvantage related to the donor-site morbidity. To solve this aspect, allografts were employed with initial promising results. Nowadays, SCR is to be considered a technically demanding and expensive procedure, because of the cost of the allograft plus that of all the anchors employed to fix it. The Arthroscopic Biceps Chillemi's technique addresses these concerns in performing SCR and presents numerous advantages being a safe, easier, time and cost-saving way compared to the other published techniques. This technique has only one *conditio sine qua non*: the presence of the long head of the biceps tendon (LHB), used as an autograft. This condition may be interpreted as a disadvantage of this procedure in the presence of some anatomic variations of the intra-articular portion of the LHB and the very rare absence of the tendon or in case of partial or complete rupture of the LHB tendon associated with a rotator cuff tear.

Keywords Rotator cuff · Irreparable · Tear · LHB tendon · Superior capsular reconstruction

#### Introduction

Rotator cuff tears are very common, and in most cases, a complete repair of even large or massive tears can be achieved [1]. However, a subset of patients exists in whom the rotator cuff tendon is either irreparable due to a fixed retraction or very poor tissue quality [2, 3]. These patients may complain a significant pain and weakness despite active overhead motion or in other cases may present shoulder pseudoparalysis [4]. In such cases, different options can be proposed. In addition to medical therapy associated with a rehabilitation program of deltoid strengthening, in the presence of concomitant arthritis and for patients who have pseudoparalysis, the reverse total shoulder arthroplasty (rTSA) seems the universally accepted option [4, 5]. The challenge is to choose the better treatment in those patients affected with an irreparable RC tear without shoulder arthritis. It appears quite clear how the surgical indications depend on the surgeon, and debridement with or without long head of biceps tenotomy, tuberoplasty, partial arthroscopic rotator cuff repair, interval slide, patch augmentation or muscular transfers may be different options for patients younger than 60 years who do not have pseudoparalysis [3, 6, 7]. Moreover, recently the superior capsular reconstruction (SCR) was proposed as a viable alternative [8]. In fact, patients with irreparable rotator cuff tears have a defect of the shoulder superior capsule which affects the motion of the humeral head, not only on the side of the lesion but in other directions as well, creating the yet known phenomenon called as "the circle concept" [9]. Capsular discontinuity is one of the causes underlying shoulder instability after rotator cuff tears [8, 10-12]. The SCR has been proposed with

Claudio Chillemi c\_chillemi@libero.it

<sup>&</sup>lt;sup>1</sup> Department of Orthopaedic Surgery, Istituto Chirurgico Ortopedico Traumatologico (ICOT), Via F. Faggiana, 1668 Latina, Italy

<sup>&</sup>lt;sup>2</sup> NCS Lab, Srl, Carpi, Italy

<sup>&</sup>lt;sup>3</sup> Clinical Orthopaedics, Università Politecnica delle Marche, Ancona, Italy

the aim to restore superior glenohumeral stability and function in the shoulder joint affected with irreparable rotator cuff tears [8, 13]. The original procedure provides the use of a fascia lata autograft that is attached medially to the superior glenoid and laterally to the greater tuberosity; additionally, the remnants of the rotator cuff tendons are side-to-side sutured with the graft (posteriorly the infraspinatus-teres minor tendon and anteriorly the subscapularis tendon) [8, 13]. The biomechanical role of the SCR was confirmed by different studies [8, 13, 14] demonstrating how the glenohumeral superior translation is significantly less when the graft is fixed medially to the glenoid than that after a tendon graft attached medially to the torn rotator cuff tendon [15]. During the last years, shoulder surgeons became interested in Mihata's original SCR technique [8], proposing some modifications, in particular regarding the choice of the graft, adapting dermal allograft [16].

SCR may be defined as a technically demanding procedure. Originally, the medial side of the graft was attached to the superior glenoid by using two anchors and, for lateral attachment of the graft, was used a transosseous technique that involved three bone tunnels created at the greater tuberosity [8]. Also this aspect was a topic of discussion, and different configurations with anchors were proposed to fix the graft laterally: To obtain a speed-bridge configuration, four anchors were advised [16].

In this paper, a novel and reproducible less-demanding all-arthroscopic SCR technique is reported with its early results. This technique has only one *conditio sine qua non*: the presence of the long head of the biceps tendon (LHB), used as an autograft [17].

## **Materials and methods**

Between January and June 2017, nine patients (four males and five females, mean age 66.4 years  $\pm$  3) with a irreparable posterosuperior RCT underwent arthroscopic SCR performed by the first author (CC) using the technique below described. Inclusion criteria were: no previous shoulder surgery, injections and infection, irreparable posterosuperior RCT without glenohumeral arthritis and stiffness. Six cases (out of nine) presented a subscapularis tendon tear: two cases with a Type II and four cases with a Type III lesion according to Lafosse classification [18]. All patients were followed up after a minimum of 6 months clinically by the visual analog scale for pain (VAS; 0 = no pain, 10 = maximum pain). The paired *t* test was used to determine whether there was a significant difference between preoperative and postoperative VAS score obtained at the latest control at 6 months. A p value of < 0.05 was considered to be statistically significant.

#### **Surgical technique**

The procedure can be performed depending on anesthesiologist preference under general anesthesia or interscalene cervical plexus block or combined and in beach-chair position or lateral decubitus according to surgeon request. A three-portal surgical technique is suggested: standard posterior (for the scope), lateral and antero-superior (working) portals. Once the irreparability of the posterosuperior RC lesion is assessed, with an intact LHB tendon (Fig. 1) is possible to perform the ABC technique. In the presence of a subscapularis tendon tear, we recommend to repair it (in accordance with the surgeon preferred technique and after the LHB distal tenotomy is performed). First of all the bone bed of the greater tuberosity is prepared with a shaver and motorized burr to obtain a wide surface decortication of the footprint providing maximum spongy bone (Fig. 2). LHB tendon originates intra-articularly from the superior glenoid tubercle and courses through the intertubercular groove of the proximal humerus. LHB tenotomy is performed distally maintaining intact its glenoid origin, so that our biceps graft is yet medially fixed. According to the surgeon preference and/or patients request is possible to perform a biceps tenodesis into the groove with a knotless anchor. Otherwise, the distal part of the LHB tendon can be left free probably producing the undesirable cosmetic effect of the Popeye sign. Once repaired the subscapularis tendon if torn, at this point is possible to fix laterally to the greater tuberosity the LHB, choosing between a two-anchor or a two-transosseous tunnel fixation technique.

#### Two-anchor lateral fixation of the LHB

A suture tape (XBraid TT-1.2 mm, Braided Polyethylene, Stryker, USA) is passed twice through the anterior border of the tendon to obtain a good fixation without any risk of cut of the suture. The same procedure is then performed with another suture tape for the posterior border of the tendon (Fig. 3). A suture limb from each medial suture tapes is criss-crossed and loaded into the eyelet of a knotless anchor (ReelX STT 4.5 mm-Stryker) that will be used for lateral fixation. A total of two anchors are placed for lateral row fixation, one anteriorly and one posteriorly (Fig. 4). Ideal placement of these anchors is approximately 5–10 mm lateral to the edge of the greater tuberosity, where the bone quality improves [19]. The anterior anchor is placed first. This knotless anchor features an incremental tensioning mechanism. The PEEK body of the anchor expands with each incremental turn of the black knob on

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**Fig. 1** Retracted rotator cuff tear (IS: infraspinatus; SSP: supraspinatus) appearance. Note the integrity of the long head biceps (LHB) and subscapularis (SSC) tendons. *Arthroscopic view*. Left shoulder. Lateral decubitus. Subacromial space. The scope is lateral (up) and posterior (down). The torn rotator cuff (RC) is retracted till the glenoid (G). The humeral head (HH) is exposed. The long head of biceps (LHB) is quite rounded. Note the synovitis

the inserter handle, expanding up to one additional millimeter in diameter under the cortical surface, to provide enhanced fixation.

These steps are then repeated for the posterolateral anchor. The result is a quick, secure and low profile fixation with excellent contact between the graft (i.e., biceps tendon) and bone.

**Fig. 2** Bone bed preparation of the greater tuberosity to obtain a wide surface decortication of the footprint providing maximum spongy bone. *Arthroscopic view*. Left shoulder. Lateral decubitus. Subacromial space. The scope is posterior. The LHB is firstly evaluated pulling a traction (up) before its distal tenotomy (down) with RF

#### Two-transosseous tunnels lateral fixation of the LHB

It is possible to prepare the two TO tunnels required for this technique, in accordance with what has yet been described [20]. The device to perform the tunnels is named Taylor Stitcher<sup>®</sup> Evo (NCS Lab s.r.l.—Medical Devices Factory, Carpi—Italy) (Fig. 5). In this case, it is necessary to perform an additional lateral more inferior portal. It permits to perform the TO tunnel through the handle screwing that controls the advancement of a Superelastic Transosseous

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**Fig.3** SCR: 2-anchor lateral fixation of the LHB. LHB tenotomy is performed distally maintaining intact its glenoid origin. Biceps tenodesis is performed into the groove with a knotless anchor. Arthroscopic view. Left shoulder. Lateral decubitus. Subacromial space. The scope is posterior. The LHB is prepared (up), passing twice a suture tape through the posterior border of the tendon with a suture passer able to retrieve the wire (middle), to obtain a loop (down) without any risk of cut of the suture. The same procedure is then performed with another suture tape for the anterior border of the tendon



**Fig. 4** SCR: 2-anchor lateral fixation of the LHB. A suture limb from each of the medial suture tapes is criss-crossed and loaded into the eyelet of a knotless anchor that will be used for lateral fixation. A total of two anchors are placed for lateral row fixation, one anteriorly and one posteriorly



Fig. 5 The Taylor Stitcher Evo, a dedicated instrument to perform the transosseous tunnel

Needle<sup>®</sup> (STN) (NCS Lab s.r.l.—Medical Devices Factory, Carpi-Italy). Thanks to its multiradius shape, led by the position limiter, the Taylor Stitcher® Evo performs TO tunnels in the footprint area. Tunnels are 3 mm in diameter and present a smooth curved morphology. Once located the lateral cortical entry point (approximately at about 15-20 mm distally to the greater tuberosity), the anterior tunnel is prepared firstly. The same procedure is repeated to prepare another TO tunnel posteriorly, leaving a minimum bone bridge of approximately 10 mm between the two TO tunnels in AP direction. The shuttle wire is then passed in one single step with the STN (having an eyelet close to the tip) through the TO tunnel so that the suture wires can be dragged into it. To make easier and safe this step is better to have a loop instead of a single extremity of the shuttle wire. It is possible to obtain it only with a CC trick (i.e., Claudio Chillemi trick) in mounting the shuttle wire into the STN (Fig. 6), so to have yet ready the shuttle wire in a loop configuration (Fig. 7). With the preferred instrumentation, the surgeon passes the

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**Fig.6** SCR: 2-TO tunnel lateral fixation of the LHB. Arthroscopic view. Right shoulder. Subacromial space. The scope is posterior. The shuttle wire is mounted into the STN in accordance with the CC trick (up) to obtain directly a loop—once the transosseous tunnel is performed and the needle comes out through the greater tuberosity (down)



**Fig.7** SCR: 2-TO tunnel lateral fixation of the LHB. Two TO tunnels are prepared starting from the lateral cortex of the humerus leaving a minimum bone bridge of approximately 10 mm between the tunnels in AP direction. The shuttle wire is then passed in one single step with the STN in a loop configuration (according to the CC trick)

loop through the biceps tendon anteriorly and posteriorly (in line with the exit hole of the TO tunnels) (Fig. 8). Each shuttle wire is then used to pass one extremity of a smooth



**Fig.8** SCR: 2-TO tunnel lateral fixation of the LHB. Both the loops are passed through the biceps tendon anteriorly and posteriorly (in line with the exit hole of the TO tunnels)



**Fig. 9** SCR: 2-TO tunnel lateral fixation of the LHB. Each shuttle wire is then used to pass through the tendon and the bony tunnels three sutures (one tape and two high resistance sutures). The tape is passed in both loops, while the high resistance sutures are, respectively, passed one in the anterior and one in the posterior loop

suture tape (XBraid TT—1.2 mm, Braided Polyethylene, Stryker, USA) and one extremity of a high resistance suture (Zipline#2, Stryker, USA) through the biceps tendon and through the TO tunnel so that one extremity of the tape is passed through the anterior aspect of the medial portion of the tendon and the anterior TO tunnel and the other one is passed through the posterior aspect of the medial portion of the biceps tendon and the posterior TO tunnel (like a reverse "U") (Fig. 9). Both extremities of the tape and of the sutures are then retrieved from the lateral cortical entry points of the tunnels through the lateral portal.

The simple sutures are passed twice, respectively, through the anterior and posterior border of the tendon (so to avoid

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**Fig. 10** SCR: 2-TO tunnel lateral fixation of the LHB. Both extremities of the tape and of the sutures are then retrieved from the lateral cortical entry points of the tunnels through the lateral portal. The simple sutures are passed twice, respectively, through the anterior and posterior border of the tendon (so to avoid any cut through the tendon) before tying the knot. The medial mattress suture is then completed performing an arthroscopic knot on the lateral cortex of the greater tuberosity

any cut through the tendon). Before knot tying, the pressure effect of the mattress suture onto the footprint can be proved by pulling the suture ends. The medial mattress suture is then completed performing an arthroscopic knot on the lateral cortex of the greater tuberosity. After tying the knot, the two extremities of the tape are cut. Later close with two simple knots the additional anterior and posterior sutures so to tightly secure the biceps (Fig. 10).

Once the LHB is fixed, it is possible to perform a partial side-to-side repair (Fig. 11) of the residual cuff over the top of the biceps passing a suture through the infraspinatus tendon and into the posterior margin of the biceps. Anterior margin convergence can aid in biceps tensioning even if sometimes the rotator interval tissues can be absent. Care should be taken not to over-constrain the shoulder anteriorly by attaching the graft to the subscapularis. This would be equivalent to closing the rotator interval. The anterior and posterior margin convergence is necessary to center the humeral head preventing subluxation. Acromioplasty is not performed, and the coracoacromial ligament is preserved so to prevent superior migration of the humeral head.

## Postoperative rehabilitation protocol

Postoperatively, the arm was placed in an abduction pillow at 20°, which was maintained for 30 days. Passive shoulder mobilization and active hand, wrist and elbow exercises started from the first day after surgery. Active-assisted







**Fig. 11** (**a**–**c**). SCR: ABC technique. Final construct. Once the LHB is fixed, it is possible to perform a partial side-to-side repair between the biceps and the residual cuff tissue. **a** *Two-anchor lateral fixation of the LHB*. **b** *Two-transosseous tunnel lateral fixation of the LHB*. **c** *Arthroscopic view*. Left shoulder. Lateral decubitus. Subacromial space. The scope is posterior. The humeral head is no more exposed and covered by the tendinous tissue of the LHB partially sutured with the remnant of the cuff (the violet knot in orthocord is fixing the posterior border of the LHB with the residual posterior cuff)

shoulder exercises were allowed from the first month postop, and from the second month strengthening exercises of the deltoid were allowed.

## **Preliminary results**

No intraoperative or postoperative complications were encountered. The LHB was laterally fixed in five cases with two anchors and in four cases with two transosseous tunnels. In no case biceps tenodesis was performed: Popeye sign was easily detected in four patients. In the remnant five cases, it was covered by the well-represented subcutaneous tissue of the superior arm of the patients. All the six subscapularis tendon tears were arthroscopically repaired in all cases with one additional anchor. The mean VAS score significantly improved from 7.2 to 2.3 (p < 0.01). No difference was found between patients with (6/9) and without (3/9) subscapularis tendon tear repaired and if the LHB was laterally fixed with two anchors (5/9) or with two transosseous tunnels (4/9). Operative time did not significantly differ between twoanchor and two-TO tunnel lateral fixation of LHB. Average case time (excluding the time necessary to repair the subscapularis tendon) in the two-anchor group varied from 46 to 58 min and from 52 to 65 min in the two-TO tunnel group.

## Discussion

During the last few years, literature mostly dealt with the treatment options available in patients affected with irreparable posterosuperior rotator cuff tears without any signs of arthritis, and superior capsular reconstruction demonstrated its efficacy [1, 21–28]. In accordance with the original technique and later modifications [8], the fascia lata autograft was fixed medially to the glenoid (with two or more anchors) and laterally to the greater tuberosity (with a compression double-row technique using four anchors or three transosseous tunnels). Additionally, side-to-side sutures were used to anteriorly and posteriorly connect the graft to the native residual rotator cuff tissue to restore anterior and posterior force couples.

However, some major concerns come out from the data available in the literature, and in particular about the choosing the graft and its fixation. The fascia lata as an autograft has a disadvantage related to the donor-site morbidity. To solve this aspect, allografts were employed with initial promising results. But, recently the biome-chanical and clinical results of the SCR using fascia lata as the graft have been compared with single-layered human dermal allograft. The latter—due to its greater flexibility, was able to partially restore superior glenohumeral stability, whereas fascia lata allograft completely restored the superior glenohumeral stability [25].

The described techniques in addition to being technically demanding are surely expensive, because of the cost of the allograft plus that of all the anchors employed to fix it. The Arthroscopic Biceps Chillemi's technique addresses these concerns in performing SCR and presents numerous advantages:

- 1. the LHB tendon is an autograft without any donor-site morbidity
- 2. the LHB as an autograft is cost-saving
- 3. the LHB as the fascia lata is a tendon and for this reason biomechanically superior to dermal allograft
- 4. the LHB tendon maintains its origin and its vascular pedicle, so it is vital
- 5. the LHB tendon is yet fixed medially to the upper part of the glenoid, and this aspect implies no needs to fix it. In other words, it means: no needs to use anchors, makes surgery easier or less demanding, reduces the operative time and consequently reduces the costs
- 6. the LHB lateral fixation does not present particular skills, being the shoulder surgeon more confident to fix a tendon into the greater tuberosity. Moreover, in comparison with the yet published technique this step is easier—quicker and cheaper employing only two knotless anchors or two TO tunnels

The only disadvantage of this procedure is represented by some anatomic variations of the intra-articular portion of the LHB and the very rare absence of the tendon [29] or as a consequence of rotator cuff tear in which LHB may be involved in partial (16%) or complete rupture (7%) [30].

In case of this evenience may be advised the employment of biologic products guided by sound evidence and cost–benefit considerations [4].

The current paper presents some conceptual similarities with the recently published "Chinese way" to reconstruct the superior capsule of the shoulder [17], with differences in the arthroscopic technique (number of portals required and lateral fixation of the tendon). In addition in this study a major concern was addressed. It is known that the LHB is considered as a shoulder pain generator [31], and its employment in the SCR could be responsible for a really discomfortable painful shoulder. For this reason, before publishing this technique we carefully clinically evaluated for the first six months all the operated patients to address this doubt. The early promising results of the ABC technique showed that the use of the SCR is safe and is not associated with an increase in postoperative pain for the first 6 months.

## Conclusion

The current technique allows to perform an all-arthroscopic SCR in a safe, easier, time- and cost-saving way compared to the other published techniques. However, even if this

technique is less demanding, the arthroscopic SCR is still an advanced procedure and should be performed only by well-prepared arthroscopic shoulder surgeons. Further clinical trials are needed to investigate the long-term benefit of this technique.

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#### **Compliance with ethical standards**

**Conflict of interest** Claudio Chillemi declares that he has no conflict of interest. Matteo Mantovani designed and manufactured the Taylor Stitcher Evo<sup>®</sup> + Superelastic Transosseous Needle<sup>®</sup>. Antonio Gigante declares that he has no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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*The rotator cuff tear repair with a new arthroscopic transosseous system: the Sharc-FT*<sup>®</sup>

# P. Baudi, E. Rasia Dani,G. Campochiaro, M. Rebuzzi, F. Serafini& F. Catani

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ORIGINAL ARTICLE

# The rotator cuff tear repair with a new arthroscopic transosseous system: the Sharc-FT<sup>®</sup>

P. Baudi · E. Rasia Dani · G. Campochiaro · M. Rebuzzi · F. Serafini · F. Catani

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#### Abstract

*Purpose* Today, in rotator cuff tear repair, the transosseous sutures are considered superior from a biological and biomechanical point of view. Our purpose is to present the early clinical and biomechanical data of a new arthroscopic rotator cuff tear transosseous repair system: the Sharc-FT<sup>®</sup>. *Materials and methods* A total of 34 patients with rotator cuff tear affecting supraspinatus and infraspinatus, 1 to 3 cm wide, were treated and evaluated from 2010 to 2013. The average age was 63.2 years. Mean follow-up was 18.6 months. All patients were assessed through Constant score in the preoperative step and at 3-, 6-, and 12-month follow-up, performing an MRI 6 months after surgery.

*Results* The patients have shown a mean preoperative Constant score of 24.5 pt that constantly increases after surgery, until a mean value of 86.9 at 12 months. Regarding complications two cases of adhesive capsulitis were recorded. *Conclusions* This device permits to obtain transosseous sutures with cortical fixation; to greatly reduce the problems of lack of bone resistance; to decrease motion at tendon–footprint interface improving fatigue resistance; to make the stress–load distribution homogeneous at the footprint, thus optimizing biological healing. A later evaluation will be necessary, especially for the incidence of retears.

E. Rasia Dani

Keywords Cuff tear  $\cdot$  Arthroscopic  $\cdot$  Transosseous  $\cdot$  Sharc-FT  $\cdot$  Suture bridge

#### Introduction

Over the past 40 years, rotator cuff tear repair techniques have undergone a remarkable evolution, permitting a gradually improved tendon to bone fixation. In 1944, McLaughlin [1] was the first to describe a transosseous rotator cuff tear repair that has represented the gold standard of the types of repair of these lesions, open or miniopen.

The advent of the arthroscopy technique has revolutionized the approach to this kind of surgery; in the last years, we have attended to the appearance of many devices of fixation: screwed or beaten anchors, made of materials like titanium, peek or reabsorbable ones. The repair techniques also evolved from single row to double row [2–5], until the development of transosseous-equivalent configurations like the suture bridge technique, to obtain a better tendon compression to the footprint interface optimizing contact area and pressure, as well as pullout strength and less interface motion [6, 7].

These surgical repair techniques have become of common use in arthroscopic approach, but the rate of pull out with poor bone stock is still high [8], as well as the rate of failure at tendon level, so the problem of rotator cuff retears is still not completely solved [9]. To improve outcomes after repair, healing biology at the footprint interface must be advanced.

The transosseous repair fixation system represents today the most reliable surgical technique from the biological and mechanical point of view, even if it still needs to be improved.

P. Baudi ( $\boxtimes$ )  $\cdot$  G. Campochiaro  $\cdot$  M. Rebuzzi  $\cdot$  F. Serafini  $\cdot$  F. Catani

Department of Orthopaedic Surgery, Policlinico Modena University, Via del Pozzo 71, 41100 Modena, Italy e-mail: baudi.paolo@policlinico.mo.it

Department of Orthopaedic Surgery, Fracastoro Hospital, Via Circonvallazione 1, 37047 San Bonifacio-Verona, Italy

The purpose of our analysis is to present the early clinical and biomechanical data of a new arthroscopic rotator cuff tear transosseous repair system: the Sharc-FT<sup>®</sup>.

#### Methods

From September 2010 to January 2013, 67 patients (31 male–36 female) were treated with an average age of 63.2 years (range 41–75) and a rotator cuff tear that affected supraspinatus and infraspinatus tendons, 1 to 3 cm wide, by MRI evaluation.

All patients were assessed with the constant score (0–100 points) in the preoperative phase and at 3-, 6-, 12-months follow-up. Six months after surgery, patients underwent a MRI for healing evaluation. We have completely evaluated 34 patients with a mean follow-up of 18.6 months (range 12.4–22.3).

The operative technique consisted of one Sharc-FT<sup>®</sup> device with its relative three sutures. A couple of the adopted configurations are sketched in the picture below reported (Fig. 1).

To minimize variability, all patients were treated by the same two surgeon (P. B., E. R. D.).

After surgery, the upper limb was immobilized in a  $20^{\circ}$  abduction sling for 30 days, passive physiotherapy was started after 10 days, while active physiotherapy after 3 weeks.

#### Surgical technique

The Sharc-FT<sup>®</sup> was developed in collaboration with NCS-LAB of Carpi (Modena, Italy) (Fig. 2).

This device is characterized by its placement, in a region with a good bone quality, located about 15–20 mm distally to the great tuberosity; management of two to four inner sutures to achieve a medial row in the footprint that can be developed also within lateral sutures in traction or compression configuration, so the possibility to perform a wide and personalized range of repairs with internal and external



Fig. 2 The Sharc-FT<sup>®</sup> with the suture wires connected to the front part and a shuttle wire to the *back surface* 

sutures; and its shape, created to maximize the resistance to pull out effect and to prevent suture-bone interaction. Its in vivo use was preceded by laboratory biomechanical tests in repaired rotator cuff tear created on young fresh frozen bovine humeri. To simulate the tears an artificial  $35 \times 10$  mm defect of thickness was performed at the supraspinatus tendon insertion after removing other tendons. This tendon lesion was repaired to its physiological footprint using four simple half stitched polyethylene sutures tied with the same force and the Sharc-FT<sup>®</sup> suture platform.

Two tests were developed: the loading cyclic test and failure test by a multi-actuator Italsigma IT08-074. In both, the device has shown good results in comparison with the data measured with other repair techniques using anchors with different suture configurations.

The Sharc-FT<sup>®</sup> application needs specific surgical instrumentations that allow guided and repeatable procedure saving operative time: the special compass (Fig. 3) permits easy passage of the shuttle transosseous sutures and the implant carrier assures a beating insertion of the Sharc-FT<sup>®</sup>, overcoming the traditional difficulties related to the transosseous arthroscopic suture repair procedures.

Patients were positioned in lateral decubitus with the operated upper limb in traction, under general anesthesia.



Fig. 1 Example of device positioning (*left*); one transosseous Mattress stitch and 2 simple stitches from the external hole (*middle*); two transosseous Mattress stitches and *closed loops* in the external hole and one simple stitch (*right*)



Fig. 3 The compass

 Table 1 Constant score results summary

Constant score	Mean	Min	Max
Presurgery	24.5	16.4	68.1
3 months	63.1	43.6	82.0
6 months	83.2	47.0	89.5
12 months	86.9	47.5	90.4

63.1 pt (min 43.6-max 82.0); at 6 months 83.2 pt (min 47.0-max 89.5); finally, at 12 months 86.9 pt (min 47.5-max 90.4) (Table 1).

At 6 months, all patients had undergone an MRI for rotator cuff and surgical repair evaluation: there was no device mobilization nor rotator cuff retear.

There were no other outstanding complications, except for two cases of adhesive capsulitis treated with prolonged rehabilitation.

instrumentations could be applied: first, the proximal 3 mm  $\emptyset$  hole on the footprint was made; and second, the guide compass could be assembled and set to perform the distal lateral 3 mm  $\emptyset$  hole 3 cm from the greater tuberosity edge. The shuttle wire could then be passed through the transosseous tunnel with the compass, so it could drag the suture wires connected to the front part of the Sharc-FT<sup>®</sup> in up to obtain the back surface of the device in contact with

After tendon preparation for suture, the surgeon pro-

ceeded with the footprint preparation creating a heavy

surface decortication with an extension of several milli-

meters with a bonecutter. Then the Sharc-FT<sup>®</sup> system

To conclude the rotator cuff tear was sutured.

#### Results

the cortical bone (Fig. 4).

The 34 operated and completely evaluated patients with a mean follow-up of 18.6 months (range 12.4–22.3) showed a mean constant score before surgery of 24.5 pt (min 16.4–max 68.1). Three months after surgery, the mean value was

#### Discussion

The rotator cuff tear represents one of the most frequent musculoskeletal lesions. In spite of numerous technological innovations, retears are still complications with extremely variable rate (Galatz et al. JBJS 2004) [10].

The first transosseous repair technique was developed by McLaughlin in 1944 [1]; since then, technological improvements, in particular with the coming of arthroscopy, have produced a very high possibility of repairing these lesions [11-13].

In rotator cuff tear repair procedures, anchors are the most commonly used devices, which can be screwed or beaten, of various kinds of materials, with 2 or 3 sutures, and permit several repair configurations (single row, double rows, suture bridge having multiple sutures configurations).



Fig. 4 The shuttle wire passage in the transosseous tunnel (left); X-ray of the Sharc-FT<sup>®</sup> implant (right)

However, possible failure induced the development of other types of sutures over the years, until the production of anchors that can allow a transosseous-equivalent repair technique [14]. The problems related to the migration and pullout of these devices, especially in patients with a poor bone stock, still represent the principle complications nowadays.

Today, the transosseous suture is considered superior in rotator cuff tear repair from a biological and biomechanical point of view [12, 13, 15]. In fact, it allows reduction of the tendon–bone gap formation, taking into consideration that a displacement of 3 mm is considered a repair failure [16]; it increases blood contribution through the tunnel, maximizing the healing potential; it enhances the contact area between footprint and the repaired tendon; it reduces stress at the repaired tendon–bone interface; and it avoids the presence of hardware on the footprint.

A recognized concern is represented by the cortical cut that can occasionally, when poor bone stock is present, modify the tunnel geometry leading to an unwanted early gap formation between tendon and footprint.

The development of an arthroscopic transosseous suture system has undergone some basic biomechanical evaluations. In the estimation of maximum load to failure, no differences between repair with anchors or with the transosseous system can be shown [17, 18]. Tocci et al's study [19] on fatigue resistance demonstrated, in high stress load, a bigger gap between tendon and bone in the repair with anchors, while in low stress load, no differences between the two systems were shown.

In anchor repair, the failure occurs at tendon level, whereas in the transosseous one in the tunnel [20, 21]. The footprint coverage has appeared greater in the transosseous technique [22–24], such as the bone–tendon interface stability [22]. The stress load is distributed much more in the bone tunnel of the transosseous repair, whereas in anchor repair, the stress load is charged to tendon and device insertion points, increasing the retear rate [25]. In addition, the pressure is homogenously delivered in transosseous sutures unlike the anchor repair, where elevated values recorded in tendon–bone interface have increased the risk of ischemic damage to tendon tissue [24].

From these biomechanical assumptions, a transosseous suture system was developed which allows conjugation of the validity of this type of repair technique with the advantages of arthroscopy: the Sharc-FT<sup>®</sup>. This device permits to obtain arthroscopic transosseous sutures with cortical fixation; to create a traction-compression lateral suture inside the footprint prepared purposely; to greatly reduce the problems of poor bone resistance; to decrease motion at tendon–footprint interface improving fatigue resistance; finally, to make the stress–load distribution at the footprint homogeneous, optimizing biological healing.

Our initial clinical experience has obtained encouraging results. In our study, we have taken into consideration the same type of rotator cuff tear affecting supraspinatus and infraspinatus, 1 to 3 cm wide: 6 months after the surgical operation, MRI examination highlighted a very good biological tendon healing without retears. Constant score values were satisfactory, except in one case, probably due to an error of surgical indication.

We did not have complications in short and long term, except for two cases of adhesive capsulitis; we noted an initial increase in surgical time compared with the anchor technique due to the learning curve in the compass use.

Nevertheless, this study shows some limitations: it is retrospective, the follow-up is still very short and the system needs to be tested in much wider rotator cuff tears.

A later evaluation will be necessary, especially for the incidence of retears.

#### Conclusions

The improvement of suture technique in rotator cuff tears has permitted a considerable increase in the possibility of a successful treatment of this pathology; nevertheless, the complication of relapses remains. From the point of view of technological evolution, a new system of arthroscopic transosseous suture has been created. This first clinical experience confirms the efficacy of this system which could have a very interesting evolutionary application.

These early clinical results are consistent with the relevant cyclic and static (ultimate tensile load) results measured in a biomechanical test set up [26] confirming that the measured mechanical primary stability could be, as reported in several previous papers, at the basis of the good clinical outcome.

**Conflict of interest** We certify that there is no actual or potential conflict of interest in relation to this article.

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# Gap formation in a transosseous rotator cuff repair as a function of bone quality



CLINICAL OMECHAN

## M. Mantovani<sup>a</sup>, P. Baudi<sup>b</sup>, P. Paladini<sup>c</sup>, A. Pellegrini<sup>d,\*</sup>, M.A. Verdano<sup>d</sup>, G. Porcellini<sup>c</sup>, F. Catani<sup>b</sup>

<sup>a</sup> NCS Lab, Carpi, Italy

<sup>b</sup> Orthopedic and Traumatology Department, University of Modena, Modena, Italy

<sup>c</sup> Unit of Shoulder and Elbow Surgery, D. Cervesi Hospital, Cattolica, Italy

<sup>d</sup> Orthopedic and Traumatology Department, University of Parma, Parma, Italy

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#### ABSTRACT

*Background:* The transosseous approach has been well known for a long time as a valid repair approach. Over time, various criticisms have been raised over this technique principally classifiable in two main categories: technical difficulty and related reproducibility in an arthroscopic environment, and repair stability (in the suturebone contact area). About cyclic performance, several authors have conceived test setups with the aim of simulating a real environment in dynamic load conditions. The aim of this study was to monitor gap formation in a cyclic test setup.

*Methods*: The performance (measured as gap formation) has been monitored as a function of bone density to verify the effect of the latter. The test blocks have been shaped using sawbones® test bricks (Malmo, Sweden) of different densities, and the following values have been tested: 10, 15, 20, 30 and 40 pcf.

*Findings:* The comparison has been made between the two groups: traditional transosseous and new approach with an interposed device. Regarding the traditional transosseous approach in a 10-pcf environment, not even the first loading cycle was completed, the whole bone bridge was destroyed in the first loading ramp and no further loading capability was present in the repair. By increasing the block density, the surface damage in the suture-block contact decreased.

*Interpretation:* With this work, it has been demonstrated how the traditional transosseous approach is strongly influenced by the bone quality up to the point where, in certain conditions, a safe and reliable repair is not guaranteed.

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#### 1. Introduction

The transosseous approach has been well known for a long time as a valid repair approach (Apreleva et al., 2002; Tashjian et al., 2008).

Over time, various criticisms have been raised over this technique principally classifiable in two main categories: technical difficulty and related reproducibility in an arthroscopic environment, and repair stability (in the suture-bone contact area). From the clinical point of view, these aspects have a direct implication in the mechanical stability and, therefore, the successful treatment of rotator cuff tears (Baudi et al., 2013).

So far, the basic drivers for an optimal repair have already been identified, and still today, they represent the state of the art. Between these basic drivers, Burkhart et al. (1997) found an optimal cyclic resistance for the avoidance of an excess tension in the repair and the need to look for a more distal area to the proximal metaphysis. About cyclic performance, several authors have conceived test setups with the aim of simulating a real environment in dynamic load conditions (Barber and Drew, 2012; Barber et al., 2010; Baums et al., 2008, 2010a,b; Bisson and Manohar, 2009; Busfield et al., 2008; Cummins et al., 2005; Dierckman et al., 2012; Kim et al., 2006; Kummer et al., 2011; Lee et al., 2005; Ma et al., 2004; Mahar et al., 2007; Mazzocca et al., 2005, 2010; Meier and Meier, 2006; Mihata et al., 2011; Milano et al., 2008; Nelson et al., 2008; Özbaydar et al., 2008; Park et al., 2007, 2008; Petit et al., 2003; Smith et al., 2006; Spang et al., 2009; Tashjian et al., 2008; Tauber et al., 2011; Tocci et al., 2008; Zheng et al., 2008).

Although a significant discrepancy is evident in both the way measurements are done and the final results provided, gap formation during cyclic loading is a fundamental parameter to be controlled in order to improve the quality and efficacy of the repair (Dines et al., 2010).

From a literature survey, it is evident that there is an absence of a sufficiently shared test protocol that adopts an objective way to assess gap formation and how the test dynamics influence the final result. An accepted and shared evaluation method would permit to objectively know when the transosseous approach is a suitable solution and

<sup>\*</sup> Corresponding author at: University of Parma, Via Gramsci 14, 43100, Parma, Italy. *E-mail address:* a.pellegrini@aol.com (A. Pellegrini).

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transform the approach into a less sensitive repair method to the test conditions

The aim of this study was to monitor gap formation in a cyclic test setup as described below.

#### 2. Methods

Gap formation was defined as the extension of the separation between tendon and bone contact. The performance (measured as gap formation) has been monitored as a function of bone density to verify the effect of the latter.

The test blocks have been shaped by sawbones® test bricks (Malmo, Sweden), made of polyurethane foam. The international standard specifications from ASTM F1839 declare that the physical properties of this material are in the order of those reported for the human cancellous bone. In particular, related to our study, previous works in literature have also reported failure strength and elastic modulus consistent with the human glenoid bone (Virani et al., 2008).

Bricks of different densities value were tested: 10, 15, 20, 30 and 40 pcf (the grade designation refers to the nominal density of the foam, as indicated in ASTM F1839).

In order to avoid any fault in the gap formation measurement, we decided to eliminate the knot tension variable. For this reason, we conceived proper grip equipment to firmly hold the sutures and to avoid them from sliding and at the same time to permit the application of the same pre-tension load in all cases without introducing superficial damages. The vertical translation was impeded firmly by using an aluminum plate fixed on the superior surface of the brick. The adopted suture clamp is presented in Fig. 1a. The four closing screws have been closed to a constant torque of 12 Nm in all test runs to avoid strand slippage in pre-test constant conditions.

The loading conditions were as follows: oscillating sinusoidal waveform from a minimum of 10 N up to 100 N and a test frequency of 0.2 Hz. A pre-tension of 10 N was applied for 1 min before starting the dynamic test, and at 500 repetitions, the test was stopped.

In Fig. 1b, the clamping system mounted on the loading machine is shown. The actuator permits to assess the loading direction; a coaxial LVDT sensor (displacement range  $\pm 100$  mm) is embedded by factory and aligned with a hydraulic actuator (Italsigma srl, Forlì, Italy) and recorded the displacement during the whole test.

The initial displacement was zeroed after this pre-load, and the sampling frequency was 100 Hz. The test end was reached when one of these two events occurred: load cycle number 500 was reached or a displacement of the vertical actuator exceeded 10 mm (the first event to occur was recorded as the test's final goal). Various authors reported analogous test loading conditions in literature (Barber et al., 2010; Baums et al., 2008, 2010a; Burkhart et al., 1997; Lee et al., 2005; Mahar et al., 2007; Petit et al., 2003).

To reproduce the transosseous repair, two different approaches were used: the first is the traditional transosseous method while the second made use of a new device named Sharc-Ft® (NCS lab srl, Modena, Italy) and a correspondent instrument named "compasso." Sharc-Ft® is an implantable device designed for the arthroscopic or open surgery in the treatment of shoulder rotator cuff tears. The device is applied by following a transosseous approach, and "compasso" is used as a mobile shuttle to obtain lateral access of the tunnel throughout the humeral head. The main advantage of the above device with respect to other techniques is to prevent the bone cutting phenomena whilst ensuring a wide-based footprint reconstruction.

The latter technique uses a titanium device in a transosseous approach to be able to isolate the direct impingement between sutures and synthetic bone. In Fig. 2, the instrument used to create the tunnel is presented, including the device in the final configuration; in Fig. 3a, we reported an example of test block in which both approaches are shown before being tested.

Three configurations with the various block densities were considered in this study: traditional transosseous approach with 2 high resistance sutures (configuration 1), Sharc-Ft® with two sutures in the tip (configuration 2), and Sharc-Ft® with two sutures in the tip folded back in a closed ring (configuration 3). Fig. 3 shows a representation of the various test configurations.

For each combination of configuration and density value, displacement was measurement 5 times. Average value and standard deviation among the 5 repetitions were calculated for each combination.

A t-test with a confidence level of 95% was performed between configuration 1 and configuration 2 and between configuration 1 and configuration 3 (instead of the ANOVA analysis for a multiple comparison).

A failure analysis of the test block was conducted to analyze which areas are affected by superficial damage and, therefore, the source of gap formation.

#### 3. Results

Results from the *t*-test comparison between the three configurations are reported in Table 1 for each pcf value of the foam. The comparison shows significant differences between the configurations, in particular, between the traditional transosseous and the new approach with an interposed device.

various test setups. In Fig. 4b, a direct comparison of the various configurations is reported. In general, for all the configurations, the higher the density pcf value, the larger the displacement (gap). More in particular,

The graphs of Fig. 4a correspond to the measured displacement in



Fig. 1. (a) Clamping system. (b) Pre-tension of the test sutures.

а



Fig. 2. Sharc-Ft® system and related instrument to create the transosseous tunnel.

the graph related to configuration 3 reports lower displacement values with respect to the other two configurations, for all the density values. A significant improvement is for pcf values of 10 and 15 (Fig. 4a), which is even more relevant in configuration 3. Differently from configurations 1 and 2, configuration 3 shows a very similar displacement in the case of 30 and 40 pcf.

Regarding the traditional transosseous approach (configuration 1), we have to report that in a 10-pcf environment, not even the first loading cycle was completed (the whole bone bridge was destroyed in the first loading ramp, and no further loading capability was present in the repair).

By increasing the block density, the surface damage in the sutureblock contact decreased (in Fig. 5, pictures of the lateral entry hole are reported as an indication of a major gap source).

#### 4. Discussion

The transosseous approach has been known as a valid repair strategy. Over time, various criticisms were made about this technique mainly ascribable to two main categories: technical difficulties mainly related to the reproducibility in an all arthroscopic environment and stability of the construct (in the suture bone contact area).

Tab	le 1
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Comparison between the various configurations and correspondent p value.

Configuration comparison	Average	SD	pcf	р
1 vs 2	10.02-4.96	0.04-0.18	10	< 0.001
1 vs 3	10.02-3.06	0.04-0.15	10	< 0.001
1 vs 2	5.51-4.10	0.24-0.13	15	< 0.001
1 vs 3	5.51-2.96	0.24-0.11	15	< 0.001
1 vs 2	3.66-3.32	0.25-0.19	20	0.007
1 vs 3	3.66-2.58	0.25-0.14	20	< 0.001
1 vs 2	3.40-2.72	0.16-0.13	30	< 0.001
1 vs 3	3.40-1.30	0.16-0.13	30	< 0.001
1 vs 2	2.34-2.34	0.11-0.11	40	1
1 vs 3	2.34-1.24	0.11-0.09	40	< 0.001

On the basis of the findings from Oguma, and further cited by Dines et al. (2010), the potential for type 2 collagen formation increases proportionally to the contact area and is therefore inversely proportional to the gap formation (defined as extension of the separation between tendon and bone contact).

The same concept was further developed by Ozbaydar (expanding the original work from St Pierre), remarking on the importance of keeping a steady contact in the initial regeneration phase (Özbaydar et al., 2008).

On the basis of the obtained results, we could conclude that the traditional transosseous approach by itself making use of high strength sutures leads to a significant increase in gap formation in a dynamic test configuration (for the effect of this impingement in the circled area, see Fig. 5).

By comparing the measured average displacement as a function of test block density, it is evident that there is a significant reduction of their values proportionally to the increase of block density.

The measured span range shifting from 10 to 40 pcf demonstrates a low reproducibility of the repair and how this is strongly affected by the bone consistency; we can therefore state that the construct stability (in terms of repair stiffness, ultimate load to failure and gap formation) is affected by bone quality, and to guarantee a successful result, it seems necessary to know the bone quality before taking the repair decision.

On the basis of our experimental experience, an effective way to mitigate this variability effect may be an increase of the number of sutures



Fig. 3. (a) Transosseous tunnel produced by "compasso" and Sharc-Ft® system in place on the left side; traditional transosseous approach on the right side. (b–d) Tested configuration: 1 (b), 2 (c), 3 (d).



Fig. 4. (a) Displacement comparison in mm (gap formation) at the end of the test (average value based on 5 repetitions; the end of the test was determined when the first of the following 2 events occurred: failure of the bone bridge and load cycle no. 500). (b) Displacement comparison in the 3 different tested configurations.

that are passed in the tunnel in order to reduce the specific tension for each.

The suture–bone contact area seems to be the principal source of gap formation in a dynamic test configuration.

From our failure investigation conducted over the tested samples, we can clearly show the reshaped areas (areas where the original tunnel geometry was different); these are principally in the following spots: lateral entry hole and internal area (where the sutures come in contact with the bone).

The experimental evidence of this work is that by avoiding a direct impingement, we significantly reduce the gap formation during the test.

This conclusion was obtained also by Salata et al. (2012), who showed how performance improvement could be obtained by introducing one or more devices isolating the direct contact with the bone.

We have to keep in mind that although there is a certain correlation between ultimate load and gap formation, this is not always true, so specific in-depth analysis must be accomplished.

This trend, intended as gap formation, was also confirmed making use of an interposed device.

Of great importance, however, is the chosen suture configuration that can maximize, when the closed ring is recreated (as indicated in configuration 3), the stability of the construct through an optimal force balance and an overall reduction of gap formation (compared to what measured in configuration 2 in which the sutures are loaded only on the tip).

Therefore, by selecting test configuration 3, we are able to reproduce a construct that is by far more reproducible varying the test bone density. In fact, the performance is constant and the bone density should no longer be considered a variable affecting the quality of the repair in a transosseous approach.

Results obtained at high values of density deserve a special remark. Authors believe that when using configuration 3 at high values of density, displacement reveals a saturation effect. This is due to the fact that, going from configuration 1 to configuration 3, the elastic factor of the suture becomes prominent with respect to other factors. For example, in configuration 2, there can still be a small angle between the device and the brick while providing tension to the suture, resulting in a longer displacement. The same cannot happen in configuration 3, where the only factor influencing the displacement belongs to the elasticity of the suture.

The stability of the repair is more affected by the environmental conditions when sutures are loaded in the device only in the tip, without closing the ring. Despite this, performance is better anyway when compared to the classical transosseous approach. This is due to the slenderness and flexibility of the design.

With this work, it has been demonstrated how the traditional transosseous approach is strongly influenced by the bone quality up to the point where, in certain conditions, a safe and reliable repair could not be guaranteed.

Moreover, by monitoring the gap formation speed and progression in a traditional repair, the gap forms in the very early stage of the test (avoiding the repair stability even in the early phase when many authors agree upon the importance of keeping a steady contact), and it never stops but proceeds continually (the test cuff off was fixed, as indicated by many authors, at 500 cycles, but even the last cycles continue to increase the gap size).



Fig. 5. Direct impingement suture/sawbones with evident marks present at the end of the test (configuration 1). The red circles contain the superficial grooves induced by the impingement.
In this study, synthetic material was used, being its physical properties in the order of the human cancellous bone. The purpose of the study was to examine what is the proper configuration that does not force the operator to know a priori the density value of the bone for each patient. An in vivo study involving real patients with different bone densities would be ideally the best method to evaluate in vivo results for a certain suture configuration. However, first, testing different suture configurations is not possible in the same bone area, and second, in vivo analysis on real patients would introduce many additional factors that can be directly related for example to the patient status and the level of lesion.

#### 5. Conclusions

What emerges from this study is the strict connection between performance and bone quality in a traditional transosseous approach and the related gap formation; the latter, as previously indicated, continues to increase over cycles and in certain density conditions cannot be considered a reliable way of fixing our tear.

Therefore, the desire of improving this result in a transosseous approach has been obtained by interposing a device isolating sutures from bone (Sharc-Ft<sup>®</sup>).

With this new approach, we avoid a direct impingement, and in the closed ring configuration (number 3), we mitigate the contact pressure and reduce the risk of local bone damage, also preventing the user to know a priori the value of bone density.

Further studies on real bones by means of cadaver specimens are required to continue the evaluation of the method in presence of muscles, under specific (passive) motions of the upper limb.

#### Sources of founding

None.

#### **Conflict of interest statement**

Author Matteo Mantovani report the following details of affiliation or involvement in an organization or entity with a financial or nonfinancial interest in the subject matter or materials discussed in this manuscript: paid employee for a company or supplier.

The rest of the authors disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work.

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#### **Technical Note**

#### Arthroscopic Rotator Cuff Tear Transosseous Repair System: The Sharc-FT Using the Taylor Stitcher

Andrea Pellegrini, M.D., Enricomaria Lunini, M.D., Manuela Rebuzzi, M.D., Michele Verdano, M.D., Paolo Baudi, M.D., and Francesco Ceccarelli, M.D.

**Abstract:** Transosseous rotator cuff tear repair was first described in 1944. Over the years, it has represented the gold standard for such lesions. Through open and mini-open approaches, as well as the arthroscopic approach, the transosseous repair system represents one of the most reliable surgical techniques from a biological and mechanical perspective. Nevertheless, further improvements are required. This article describes an arthroscopic rotator cuff tear transosseous repair system, developed in collaboration with NCS Lab (Carpi, Italy): the Sharc-FT using the Taylor Stitcher. Our first experience in the clinical application of the arthroscopic technique using the transosseous suture system has shown encouraging clinical outcomes, confirming its efficacy. The patient satisfaction rate was high, and no patient expressed concern about the implant. The complication rate was very low. By improving the suture technique in the treatment of rotator cuff tears, a remarkable increase in the success rate in the treatment of this pathology could be reached; nevertheless, complications such as retears of the rotator cuff still occur.

'n 1944 McLaughlin<sup>1</sup> was the first author to describe a transosseous rotator cuff tear repair. Over the years, it has represented the gold standard for such lesions, by means of an open or mini-open approach. In the past several decades, rotator cuff repair techniques have undergone a remarkable evolution, improving tendon-to-bone fixation. The advent of arthroscopy has brought a new framework in rotator cuff surgery, supported by the introduction of many devices for fixation over the past few years: screwed or impacted anchors, made of different materials, can be arranged using many different types of repair configurations. Despite such improvements, rates of pullout with poor bone stock are still very high, as are rates of failure at the tendon level. Therefore the complication of a rotator cuff retear has not been completely solved yet.<sup>2,3</sup> To improve outcomes after repair, healing biology at the footprint

© 2015 by the Arthroscopy Association of North America 2212-6287/14859/\$36.00 http://dx.doi.org/10.1016/j.eats.2015.01.005 interface must be carefully considered. The transosseous repair system represents one of the most reliable surgical techniques from a biological and mechanical perspective. Nevertheless, further improvements are required.<sup>4-7</sup>

This work describes an arthroscopic rotator cuff tear transosseous repair system, developed in collaboration with NCS Lab (Carpi, Italy): the Sharc-FT using the Taylor Stitcher (Video 1, Figs 1-11).

#### **Technique**

Under general anesthesia and with a routine antibiotic regimen, the patient is positioned in the lateral decubitus position, lying on the nonoperative side. The nonoperative arm is tucked to the side, whereas the operative extremity is placed into an arm holder. Axial traction is applied while the operative arm is slightly flexed forward  $(10^{\circ})$  and internally rotated (as shown in Fig 1 and Video 1).

The table can be rotated by  $20^{\circ}$  toward the operator so that the glenoid is parallel to the floor, working as a reference for positioning. The superficial anatomic landmarks and arthroscopic portals are then carefully marked.

A standard posterior viewing portal is created in the "soft spot," and a 30° arthroscope is introduced into the joint. Inspection for intra-articular pathologies is performed.

Diagnostic arthroscopy and intra-articular evaluation of the cuff tear are performed. A lateral portal is made

From the Orthopaedic and Traumatologic Department, University of Parma (A.P., E.L., M.V., F.C.), Parma; and Orthopaedic and Traumatologic Department, University of Modena (M.R., P.B.), Modena, Italy.

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Address correspondence to Andrea Pellegrini, M.D., Orthopaedic and Traumatologic Department, University of Parma, Via Gramsci 14, Parma 43100, Italy. E-mail: a.pellegrini@aol.com

#### ARTICLE IN PRESS

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**Fig 1.** The Taylor Stitcher is supplied together with 3 additional and complementary tools: an inserter, a punch, and a multipurpose tool for fitting/removing the superelastic transosseous needle. The punch is useful especially in case of osteopenic bone, in which the tunnel must be delicately and softly made to avoid crushing the lateral cortical bone.

using an 18-gauge spinal needle by which, if necessary, debridement for superior labral fraying or other intraarticular pathology can be performed.

If a biceps tenotomy is required, it is performed with a shaver. This procedure allows the surgeon to retract the tendon away from the joint, toward the bicipital groove. The degenerated tendon margins are then debrided, and the bony bed on the greater tuberosity is prepared using a bone-cutting shaver.

The arthroscope is transferred to the subacromial space. The subacromial space is then cleared of bursal tissue and adhesions to enhance visualization of the rotator cuff tear. In most cases a subacromial decompression is performed.

The mobility of the rotator cuff is assessed. If necessary, further releases are performed to ensure a low-tension placement of the tendon into its anatomic position.

If the rotator cuff is easily reducible to the lateral aspect of the greater tuberosity, then an optimal transosseous suture repair can be performed. The first step of the repair is to make a transosseous tunnel using the Taylor system, as shown in Figure 1. The superelastic transosseous needle (STN) is assembled on the



**Fig 3.** The use of the targeting needle assembled on the targeting system allows one to locate the medial transosseous exit hole.

instrument (Taylor Stitcher) and allows the creation of one or more transosseous tunnels, having in common a lateral entry hole in which the implantable device (Sharc-FT) will be inserted (Fig 2). One or more medial exit holes (Video 1) will also be created. The STN is a superelastic needle, able to recover its original shape. By using the STN with the Taylor Stitcher as a targeting device, transosseous curved tunnels having the original memorized shape (exploiting the superelastic effect) can be made. The use of the targeting needle assembled in the targeting device allows one to locate the medial transosseous exit hole (Fig 3). The Taylor Stitcher is supplied with 3 additional tools: an inserter, a punch, and a multipurpose tool for fitting/removing the STN (Fig 1). The punch is useful especially in case of osteopenic bone, in which the tunnel must be delicately and softly made to avoid crushing the lateral cortical bone. The punch allows a hole to be made where the Sharc-FT device (Fig 2) is inserted. The Sharc-FT is an implantable device specifically designed for the treatment of rotator cuff tears. It can be applied in both arthroscopic and open surgery through the use of the dedicated instrument (Taylor Stitcher). The combined use of such devices allows one to anchor the tendons to the footprint using transosseous sutures, maintaining



Fig 2. Sharc-FT device.



**Fig 4.** The targeting needle is aligned with the longitudinal axis of the humerus to find the correct lateral position of the Sharc-FT.

#### ARTICLE IN PRESS TRANSOSSEOUS ROTATOR CUFF TEAR REPAIR



**Fig 5.** Loading of a No. 1 monofilament suture (4 metric) on the distal eyelet of the superelastic transosseous needle.

contact between the implant and the lateral cortex of the humerus. By means of transosseous high-strength sutures, a wide-based construct (footprint reconstruction) is provided, together with strong anchoring of the tendon to the humeral head, avoiding the "bone-cutting" phenomenon.

The surgical technique starts by aligning the targeting needle with the longitudinal axis of the humerus to identify the correct lateral position for the Sharc-FT (Video 1), as shown in Figure 4. The previously described punch instrument is used to make the entry hole (Video 1). The next step is to load a No. 1 monofilament suture (4 metric) on the distal eyelet of the STN (Fig 5). The proximal handle is turned counterclockwise up to the rotation mechanical stop, until only the tip of the STN is outside the sleeve with the shuttle suture (Fig 6, Video 1). The distal end of the Taylor Stitcher is positioned on the previously prepared hole. The targeting needle is inserted through the targeting guide, and the position of the tip is verified so that it is pointing to the desired exit area. If the resulting position is different from what was planned, the targeting needle must be extracted entirely, the orientation of the Taylor Stitcher is corrected, and this sequence is repeated until the correct position of the STN exit in the footprint is found. Attention must be given to completely screw the targeting needle to obtain a correct targeting indication.



**Fig 7.** The high-resistance suture limbs are tied to the monofilament suture shuttle, and its medial strand is pulled to drag the high-resistance suture limbs through the tunnel.

Now, the Taylor Stitcher proximal handle is turned clockwise (2 rounds). The back protruding knob is gently hammered, with the hammer used to push over the STN for about 2 cm. The step is repeated until the STN protrudes 1 cm out from the footprint. Then, the proximal handle is turned counterclockwise (one-half round) to relax the monofilament suture, allowing an easy capture of the monofilament using a grasper (Video 1). The targeting needle is extracted, and the proximal handle is turned counterclockwise until the STN comes out from the bone.

At this point, it is necessary to set up the Sharc-FT by attaching the Sharc-FT and the insertion tool together using the retention suture and loading up to 4 highresistance sutures (5 sutures shall be considered out of standard) on the Sharc-FT distal eyelet. The highresistance suture limbs are tied to the monofilament suture shuttle, and its medial strand is pulled to drag the high-resistance suture limbs through the tunnel (Fig 7). When performing this step, we recommend using a superolateral portal to pull the sutures.

The high-resistance sutures are pulled to allow the Sharc-FT to be positioned correctly by passing through



**Fig 6.** The proximal handle is turned counterclockwise up to the rotation mechanical stop so that only the tip is outside the sleeve with the shuttle suture.



**Fig 8.** The high-resistance sutures are pulled to allow the Sharc-FT to be positioned correctly by passing through the deltoid. The Sharc-FT is inserted in the lateral hole; a gentle hammering or a simple dragging of the device by the frontal loaded sutures could be required.

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**Fig 9.** The device is unlocked with the insertion tool, leaving in place the retention suture in the proximal eyelet.

the deltoid. The Sharc-FT is inserted in the lateral hole. A gentle hammering or a simple dragging of the device by means of the frontal loaded sutures could be required; by keeping these tensioned during the insertion (Fig 8), the sutures will be in the correct position. The supporting under-head of the Sharc-FT must be pushed to obtain cortical contact, avoiding falling through the cortex. The device is then unlocked using the insertion tool, and the retention suture in the proximal eyelet is left in place (Fig 9).

At this point, lesion repair can start by passing all suture limbs through the cuff and tying the knots using the proper configuration, defined based on the lesion's characteristics and the number of sutures available (Fig 10). Finally, the surgeon needs to close the transosseous ring, bringing the anterior limb of the retention suture to the anterior portal, with its posterior limb and one strand for each suture in the lateral portal. The suture strands are tied out of the lateral portal with the posterior limb of the retention suture. One knot for each suture allows an easier pass. The suture strands are drawn through the proximal eyelet by pulling the anterior limb of the retention suture, and the knots are tied (Fig 11). The described configuration in Figure 11 is only one of the possible alternatives; the described device should be considered a platform hosting sutures for different repair approaches occurring case by case.



**Fig 10.** Knots are tied using the configuration that was previously identified as optimal based on the lesion's characteristics and the number of sutures available.



**Fig 11.** The suture strands are drawn through the proximal eyelet by pulling the anterior limb of the retention suture, and the knots are tied.

The skin incisions are finally closed in a standard fashion. The final radiographic result is shown in the final part of Video 1.

After surgery, the shoulder is immobilized for 4 weeks using a brace applying 15° of abduction and neutral rotation. During this 4-week period, only passive exercises with abduction and forward flexion are allowed. From 4 weeks onward, full range of motion is developed stepwise, starting with active exercises aimed toward strengthening the rotator cuff and deltoid muscle.

#### Discussion

The described transosseous suture system, Sharc-FT, combines the validity of such a repair technique with the advantages of arthroscopy (Table 1). This device allows one to obtain arthroscopic transosseous sutures with cortical fixation; create a traction-compression lateral suture inside the footprint; greatly reduce the problems of poor bone resistance; decrease motion at the tendon-footprint interface, improving fatigue resistance; and make the stress load distribution at the footprint homogeneous, therefore optimizing biological healing.<sup>7</sup>

Our first experience in the clinical application of the arthroscopic technique using the transosseous suture system has shown encouraging clinical outcomes,<sup>6</sup> confirming its efficacy. The patient satisfaction rate was high, and no patient expressed concern about the implant. The complication rate was very low.

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Advantages
Completely arthroscopic procedure
Transosseous repair with biomechanical advantages and no
hardware in footprint area
Decortication of footprint area
Good option for cuff repair revision with no mandatory screw
removal from previous procedure
Disadvantage
Learning curve linked to new device

#### TRANSOSSEOUS ROTATOR CUFF TEAR REPAIR

Similar to other surgical techniques, the presented technique requires time for surgeon adjustment and the learning curve could be high for young surgeons with limited experience in rotator cuff repair. In addition, the surgical time could be lengthened, and the surgeon should take this into consideration both for patient anesthesia and for the operating room time schedule.

It must be noted that by improving the suture technique in rotator cuff tears, a remarkable increase in the success rate in the treatment of this pathology could be reached; nevertheless, complications such as retears of the rotator cuff might still occur. However, further steps in the evolution of the presented system and technique, as well as improvements, can be expected in the future.

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# Surgical <u>Technique</u> Taylor Stitcher EVO

## **Taylor Stitcher EVO**

is designed to simplify the tunnel creation in RCR.



**Based on Taylor Stitcher technology**, in this release we implemented a different targeting frame that permits an **easy orientation in the shoulder** together with a **proper identification of the lateral entry spot** without measuring it in advance.

A nitinol needle, 1,9 mm in diameter, is activated and in one single step, we can create the transosseous tunnel and pass the suture/shuttle.

The rounded smooth shape of the tunnel **avoids sharp corner** formation and reduces the main sources of gap formation.

The movable targeting frame permits an **easy insertion** and provides the possibility of reaching each point of the foot-print area to create your **optimal fixation**.

The bone bridge is 18-20 mm.

**Multiple configurations are possible:** multiple parallel tunnels, multiple exits spanning from the same lateral entry hole.

**Reduced dimensions and improved manageability** are key features of these device.



#### PERFORM THE BURSECTOMY

taking care to release the deltoid fascia and the lateral bursa, prepare the margin of the lesion. Exposition of the cancellous bone is recommended.

#### NOTE:

1. In addition to the common lateral portal (permitting to get a direct tangent access to the greater tuberosity area) create an additional portal shifted distally 1-1,5 cm.

2. It is suggested to use a posterior lateral portal for optic (for a better view of the lateral entry hole).

PROXIMAL LATERAL

DISTAL LATERAL

### LATERAL WORKING PORTALS POSITIONING

Use the common lateral portal to insert the targeting frame. Subacromial working/viewing portal placed 2 cm lateral to the edge of the acromion in line with the lateral orientation line.

The check for a correct alignment, the targeting frame must be tangent to the greater tuberosity foot-print.

Be careful not be place the lateral portal not too anterior; it is recommended to place the portal close to the coronal plane (this permits the creation of multiple parallel tunnels from posterior to anterior).

Create a second lateral portal 1,5 cm distal to the above (1 finger from the previous) as a working portal for the STN cannula insertion.

#### LOADING OF THE SUTURE SHUTTLE

Load a suture shuttle (e.g. PDS size 1) or directly a suture into the tip eyelet (as in the figure). Retract the STN needle by acting on the posterior gray knob (rotate counter-clockwise) until the mechanical stop is reached.

Check for the correct STN tip exposure (as in figure) and re-position the knob on the lateral side (rotating clockwise).





Before introducing the STN cannula into the distal lateral portal, clean carefully the subdeltoid space and create an appropriate free working volume.

Use the distal portal to insert the STN cannula with the targeting frame locked in a retracted position.

Free the STN tip from soft tissues by pushing the device tip over the great tuberosity in a movement from down to top and retract the tool to find the correct entry spot.

Once in contact with the lateral cortical bone, let the targeting frame slide into the more proximal lateral portal until it reaches the foot print are of interest.

Lock the targeting frame once in position.

#### POSITIONING OF THE TARGETTING ARM

Position the targetting arm in the footprint area where the fixation point must be created. The device rigidly detects the lateral entry spot.

Keep the lateral cannula (containing the STN needle) firmly in contact with the cortical bone while tapping on the lateral piston. Be careful not tapping when the gray knob is in contact with the main body of the device.





#### EMERSION OF THE STN NEEDLE

Stop tapping when the needle and the suture shuttle emerge in the targeted area.

Before grabbing the suture shuttle with a suture grasper, act counter-clockwise on the gray knob to slightly retract the STN needle (this would permit an easier grabbing when the shuttle folds).

Once the shuttle is grabbed retract completely the STN needle by counter-clockwise rotating the gray knob until a mechanical stop is reached.

#### **REMOVE THE DEVICE, LEAVE THE SUTURE**

Remove the device from the shoulder, leaving the shuttle suture within the newly created transossoeus tunnel.





# BIOMECHANICS OF TRANSOSSEOUS APPROACH



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#### First Announcement

TRANSOSSEOUS RCR ACADEMY FEBRUARY 7th, 2017

HUMANITAS

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# ATRCR The Science BIOMECHANICAL EVALUATION

## Arthroscopic Transosseous RCR REVISITING HISTORY

- Burkhart et al. Arthroscopy, 2000
- Barber et al. Arthroscopy, 2010
- Jost et al. JBJS, 2012



Figure 3-3 A: With one suture per anchor there are five fixation points for a three-anchor construct. B: With two sutures per anchor there are eight fixation points for a three-anchor construct.



"Increasing the number of sutures crossing the repair site increases the load to failure and decreases gap formation under cyclic loading"

## Arthroscopic Transosseous RCR BIOMECHANICS

### Advantages

• Large Foot print coverage

• Uniform pressure distribution and greater stability at bone tendon interface

More even stress distribution (elimination of spikes)

Good resistance to gap formation with high load level

• Transosseous tunnel stability

2001 Richard O'Connor Award Paper

### Rotator Cuff Tears: The Effect of the Reconstruction Method on Three-Dimensional Repair Site Area

Maria Apreleva, Ph.D., Mehmet Özbaydar, M.D., Peter G. Fitzgibbons, B.A., and Jon J. P. Warner, M.D.





TABLE 1.	Insertion-Site and	Repair-Site A	reas for SS	S Before a	nd After Four	Surgical	Reconstructions
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	Original SS	SAS	SAM	TOS	ТОМ
Insertion area (% of original SS)	$\begin{array}{c} 100\\ 432\pm40\end{array}$	$67 \pm 7$	$66 \pm 7$	$85 \pm 10$	$67 \pm 10$
Insertion/repair (Site area, mm <sup>2</sup> )		293 ± 35	290 ± 31	$371 \pm 45$	$295 \pm 51$

### Tendon-Bone Interface Motion in Transosseous Suture and Suture Anchor Rotator Cuff Repair Techniques

Christopher S. Ahmad,\* MD, Andrew M. Stewart, MD, Rolando Izquierdo, MD, and Louis U. Bigliani, MD



**Figure 6.** A, the transosseous technique compresses the tendon to the footprint, creating broad fixation. B, the suture anchor places the tissue in the proximity of the footprint with limited area of fixation.

The relative movement between tendon and bone IS SIGNIFICANTLY INFERIOR IN A TRANSOSSEOUS (T) APPROACH IF COMPARED TO ANCHORS REPAIR

# Contact Area, Contact Pressure, and Pressure Patterns of the Tendon-Bone Interface After Rotator Cuff Repair

Yilihamu Tuoheti, MD, Eiji Itoi,\* MD, Nobuyuki Yamamoto, MD, Nobutoshi Seki, MD,



**Conclusions:** The double-row technique produced the greatest contact area and the second-highest contact pressure, whereas the single-row technique created the highest contact pressure and the least contact area. The transosseous technique produced the second-greatest contact area and the least contact pressure.

### ARTHROSCOPIC ANCHORLESS TRANSOSSEOUS RCR The Biomechanics

- Mikek 2011
- Green 2012
- Piza 2013
- Srikumaran 2016

# **Biomechanical Evaluation of ATRCR**





Mikek M, et al. SECEC Closed Meeting, 2011

# **Biomechanical Evaluation of ATRCR**



## **No Statistical Difference**

Double Row, Suture Bridge, and Arthro-Transosseous Repairs

Courtesy of Martin Mikek, SECEC 2011

# **Biomechanical Evaluation of ATRCR**



## **No Statistical Difference**

Double Row, Suture Bridge, and Arthro-Transosseous Repairs

Courtesy of Martin Mikek, SECEC 2011

In Vitro Biomechanical Comparison of Arthroscopic Transosseous- Equivalent and Transosseous Rotator Cuff Repair Techniques

## Andrew Green MD, Pedro Piza MD, David Paller, MS

Division of Shoulder and Elbow Surgery Department of Orthopaedic Surgery Warren Alpert Medical School, Brown University Providence, Rhode Island

**Nice Shoulder Course 2012** 

# **Repair Gapping-Low Load**

("low load": Supraspinatus, Infraspinatus, and Subscapularis loaded 500 cycles at 1 hz to 45 N, 79 N, and 109 N

	(	Gapping (mm	)				
Low Load	Group 1	Group 2	Group 3	p value	1-β		
Anterior (max)	1.74 ± 0.97	2.14 ± 0.90	1.36 ± 0.75	0.961	0.049		
Posterior (max)	$1.83\pm0.88$	2.87 ± 1.21	1.56 ± 1.34	0.281	0.097		
Maximum 🌔	2.17 ± 0.91	3.08 ± 0.91	1.85 ± 1.23	0.089	0.312		
n completed test	8	7	7				
NO FA	NO FAILURES UNDER LOW LOAD CONDITIONS						

# Repair Gapping-High Load

("high load": Supraspinatus, Infraspinatus, and Subscapularis loaded 500 cycles at 1 hz to 117 N, 205 N, and 283 N

Gapping (mm)							
	0	0	0		4.0		
High Load	Group 1	Group 2	Group 3	p value	1-b		
Anterior (max)	2.98 ± 0.94	4.46 ± 1.62	3.00 ± 1.48	0.169	0.188		
Posterior (max)	3.78 ± 1.50	5.47 ± 1.93	2.85 ± 1.63	0.078	0.350		
Maximum	3.94 ± 1.47	5.78 ± 1.50	3.40 ± 1.57	0.062	0.399		
n completed test	6	5	5				
<b>5 FAILURES UNDER HIGH LOAD CONDITIONS</b>							

Courtesy of Andy Green, NSC 2012

# Conclusions

# TRANSOSSEOUS REPAIR or TOE SUTURE BRIDGE?

- The techniques demonstrate no statistical difference
- Initial fixation strengths are equivalent

# • Failure modes are technique specific

- Bone cutout at ultimate failure 11/14 TO repairs
- Suture slippage thru lateral anchor 5/8 TOE repairs

• Surgical Technique Should be Based Upon Surgeon's Preference<sub>Courtesy of Andy Green</sub>, Nice 2012



### **Surgical Techniques**



#### TOE repair construct

ORTHOPAEDIC SURGERY

1. Isolated supraspinatus 25 mm tear

2. *(A)* Transosseous equivalent (TOE) double loaded 6.5 mm Twinfix titanium anchors (medial), Footprint 4.5 PEEK anchors (lateral); *(B)* ArthroTunneler (AT) device; simple suture configuration



Anchorless transosseous repair



JOHNS HOPKINS

Uma Srikumaran MD

### **Biomechanical Performance Comparison of Techniques**

	TOE (Anchors)	AT (Tunnels)	P-Value
Maximum Load, N	<mark>578.5</mark> ±123.8	<mark>468.7</mark> ±150.9	0.034
Stiffness, N/mm	$96.4 \pm 20.9$	91.6±13.8	0.2
First cycle excursion, mm	<mark>2.97</mark> ±1.97	4.70±2.04	0.046
Cyclic Elongation, %	8.49±7.26	$5.05 \pm 1.42$	0.11

Data are expressed as mean  $\pm$  SD.

TOE, transosseous-equivalent repair with anchors;

AT, traditional transosseous repair with Arthrotunneler

Courtesy of Uma Srikumaran, Publication Pending 2016

## Failure modes by repair group

Failure Mode	TOE (Anchors)	AT (Tunnels)	
Bone	0	1	
Type 1 <sup>a</sup>	2	6	
Type 2 <sup>b</sup>	7	2	
Mixed <sup>c</sup>	1	1	



Majority of anchor repair failures were at the musculotendinous junction

Majority of tunnel repair failures were at the bone tendon interface

<sup>a</sup> Type 1: cuff tissue repaired at the insertion site of the rotator cuff was not at all observed to be remaining on the greater tuberosity. <sup>b</sup> Type 2: remnant cuff tissue remained at the insertion site despite retear.

## <sup>c</sup> Mixed: combination of type 1 and type 2 tears, with medial and lateral tendon failure. **Courtesy of Uma Srikumaran, Publication Pending 2016**

# Conclusions

- Transosseous-equivalent anchor repair is biomechanically superior to transosseous repair in regards to ultimate load to failure and first cycle excursion.
- Tunnel transosseous repair can achieve a high load to failure ( > 450 N)
- Tunnel transosseous repair tends to fail at the bone tendon interface, while anchored TOE anchor repairs tend to fail at the musculotendinous junction.

### A Laboratory Comparison of a New Arthroscopic Transosseous Rotator Cuff Repair to a Double Row Transosseous Equivalent Rotator Cuff Repair Using Suture Anchors

Frederick J. Kummer, Ph.D., Michael Hahn, M.D., Michael Day, B.S., M.Phil., Robert J. Meislin M.D. and Laith M. Jazrawi M.D.





Discussion: Biomechanical testing suggests that arthroscopic, transosseous rotator cuff repair using a Xbox suture configuration is similar in strength and stability to an arthroscopic transosseous equivalent suture-bridge repair. Both techniques demonstrated difficulty in maintaining the lateral position of the tendon.

## **FAILURE MODE**

- **BURKHART** : with T. 40% tunnel failures, with anchors 90% of failure at the tendon interface
- MEIER : in T. with simple stitches 75% tunnel failures, with anchors repair and simple stitches (SS) 55% suture failure, 45% at tendon level
- **GORADIA**: 78% failure at tunnel level in T. and 75% at tendon level with anchors

**Conclusion:** 

in a T. approach the failure occurred at the tunnel level with anchors occurred at tendon level



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#### **Original Article**

#### Braided tape suture provides superior bone pull-through strength than wire suture in greater tuberosity of the humerus

Benjamin Leger St-Jean <sup>a,b</sup>, Jérémie Ménard <sup>c</sup>, Stéphanie Hinse <sup>a,b</sup>, Yvan Petit <sup>d</sup>, Dominique M. Rouleau <sup>a,b,\*</sup>, Marc Beauchamp <sup>a,b</sup>

<sup>a</sup> Department of Orthonaedic Suraery, Université de Montréal, Montreal, H3T 114, Canada





Conclusions: Transosseous braided tape suture provides almost twice the bone pull-through strength and is slightly correlated to volumetric bone mineral density.

# **Do We Really Need So Many Implants?**

## Arthroscopic Transosseous RCR



### **Suture Anchors**



# Thank You


# The transosseous return, new potentiality in rotator cuff repair: biomechanical rational and clinical outcome

Orthopedy and traumatology group UNIVERSITY OF MODENA AND REGGIO EMILIA Chief : PROF.F.CATANI



## why.....

...rotator cuff repair approaches evolved from a single medial row to configurations that mimic the transosseous effect (double row and suture bridge) up to the more recent transosseous repair





### From a biomechanical stand point

transosseous repair has shown over time many advantages and some limits ...

- Large Foot print coverage
- Uniform pressure distribution and greater stability at bone tendon interface
- More even stress distribution (elimination of spikes)
- Good resistance to gap formation with high load level
- Transosseous tunnel stability



## WIDER FOOT-PRINT COVERAGE

 APRELEVA 2002 : in tears 2 cm large comparing single stitches in T vs 2 mattresses in a T. vs 2 anchors single stitches vs 2 anchors mattress stitches

#### 20% larger foot print in transosseous (T) repair

MEIER 2006 : tears 2 cm large comparing 2 simple stitches in T. vs 2 anchors and simple stitches

25% larger foot print in transosseous (T) repair

**TUOHETI 2005** : tears 2 cm large comparing 2 Mason Allen vs 2 anchors with single stitches

31% larger foot print in transosseous (T) repair



#### Tendon bone interface mobility

• AHMAD C.S. A.J.S.M.

The relative movement between tendon and bone IS SIGNIFICANTLY INFERIOR IN A TRANSOSSEOUS (T) APPROACH IF COMPARED TO ANCHORS REPAIR

TOCCI JSES 2008

LARGE LESIONS TESTED WITH 2-3 MASON.ALLEN VS ANCHORS AT LOW LOAD LEVEL FOR 4000 CYCLES AND AT HIGH LOAD LEVEL FOR 2000 CYCLES NO SIGNIFICANT DIFFERENCE AT LOW LOAD LEVEL GAP FORMATION IS BIGGER AT HIGH LOAD LEVEL WITH ANCHORS

## PRESSURE AT THE INTERFACE BONE-TENDON

• TUOHETI A.J.S.M.

## THE AVERAGE PRESSURE IS 18-20% BIGGER IN ANCHOR REPAIR

SPIKES PRESENCE IS THE AREAS AROUND THE ANCHORS AND VERY LOW IN BETWEEN THE ROWS

#### GREATER HOMOGENEITY IN A T REPAIR IN TERM OF PRESSURE VALUES



#### MAXIMUM LOAD AT FAILURE



CRAFT JSES 1996

 2 MATTRESS STITCHES IN A T. APPROACH TESTED AT 35 MM/SEC (FAST) VERSUS 2 ANCHORS WITH MATTRESS STITCHES
228 N. VS 180-250 DEPENDING ON ANCHORS MODEL

BURKHEAD CLIN ORTHOP REL RESEARCH 2007 3 SUT. MATTRESS T. VERSUS 3 ANCHORS TESTED AT 6 MM/MIN (SLOW) NO SIGNIFICANT DIFFERENCE

NO SIGNIFICANT DIFFERENCES BETWEEN T. AND ANCHORS BOTH AT SLOW AND FAST SPEED TEST

## FATIGUE RESISTANCE



(75 N FOR 50 CYCLES THEN 100 N FOR 50 CYCLES THEN PROGRESSIVE INCREASE OF 25N UP TO FAILURE )

PIETSCHMAN

3 ANCHORS VS DOBLE TRANSOSSEUS REPAIR IN OSTEOPENIC AND HARD BONE

<u>RESULTS</u>

**NO SIGNIFICANT DIFFERENCE IN HARD BONE WITH BOTH APPROACHES** 

OSTEOPENIC BONE REDUCTION OF UTS FROM 190-200N TO 120-150 N, ON AVERARE TRANSOSSEOUS RESULT IS INFERIOR TO ANCHORS AND THE FAILURE MODE IS DIFFERENT

**100% TUNNELS FAILURE IN T.** 

**70% PULL-OUT WITH ANCHORS** 

## **FAILURE MODE**



- **BURKHART** : with T. 40% tunnel failures, with anchors 90% of failure at the tendon interface
- MEIER : in T. with simple stitches 75% tunnel failures, with anchors repair and simple stitches (SS) 55% suture failure, 45% at tendon level
- GORADIA : 78% failure at tunnel level in T. and 75% at tendon level with anchors
- WALTRIP : T. with Mason Allen 100% tunnel failure , with resorbable anchors and SS 100% anchors pull out !

#### **Conclusion:**

in a T. approach the failure occurred at the tunnel level with anchors occurred at tendon level

## SUMMARY



- The anchors based repair evolved from single medial row to approaches that mimic the transosseous effect (Transosseous equivalent or suture bridge)
- The transosseous repair shows some advantages pressure distribution, absence of spikes, greater stability at tendonbone interface, fatigue resistance at high load level, foot print coverage

The most evident limit is at the tunnel level: tunnel failure at high load with osteopenic bone



#### Anchors

#### Transosseous

	Contact area (tendon – bone)	
	Stress distribution	
	Gap formation	
	Hematic supply	
	Hardware presence in the foot print	
	Pull-out and intra articular migration risk	Not possible
	What in case of poor bone quality	
tendon	Failure	tunnel





Main limitation

THE EVIDENCES OF MECHANICAL SUPERIORITY OF T. AND T.O.E. HAVE SOME CLEAR LIMITATIONS :



#### **BIOLOGICAL FACTORS ARE NOT CONSIDERED**

- VASCULAR COMPROMISING DUE TO THE MEDIAL SUTURES OR THE EXCESSIVE PRESSURE
- **RESIDUAL ELASTICITY** OF THE TENDON
- TENDON RESIDUAL LENGTH NOT COMPARABLE TO THE ORIGINAL ONE

## IN TRANSOSSEOUS EQUIVALENT (T.O.E.) THE MULTIPLE IMPLANTS RISK IS NOT CONSIDERED

- GREATER TUBEROSITY FRACTURE RISK
- DIFFICULTY IN CASE OF REVISION FOR EXCESSIVE HARDWARE PRESENCE IN THE FOOT PRINT
- COST INCREASE ( 4 ANCHORS FOR T.O.E. )



## FROM A CLINICAL STAND POINT

#### SARIDAKIS P JBJS 2010

- REVIEW 6 PAPERS SR VS DR
- IN A SUB ANALYSIS DR WITH MA STITCHES SHOW A BETTER CLINICAL SCORE AND A REDUCED RE-TEAR INCIDENCE WHEN TEAR SIZE IS GREATER THAN 3 CM
- N° OF ANCHORS FAIRLY DOUBLE (1-4 vs 2-7)

#### DINES JS AAOS 2010

- RE-TEAR INCIDENCE AND CLINICAL OUTCOME COMPARABLE IN SMALL LESION
- T.O.E. SUPERIOR WITH TEAR SIZE GREATER THAN 3 CM



#### PAULY S ET ALL KSSTA 2010

• RECOMMENDED T.O.E. AND T. IN LESION WIDER THAN 3 CM OR IN PRESENCE OF DELAMINATION OF THE INFRASPINATUS

#### DUQUIN T R ET ALL AJSM 2010

 REVIEW 23 PAPERS (1532 PATIENTS ) COMPARISON OF RE-TEAR INCIDENCE IN T.O.E. AND SR

SIGNIFICATIVELY DIFFERENT THE RE-TEAR
INCIDENCE

LESION 1-3 CM 7% VS 17%

LESION LARGER THAN 3 CM 41% VS 69%



## WHICH COULD BE THE ARTHROSCOPIC TRANSOSSEOUS IDEAL REPAIR?

- MANTAIN OR IMPROVE THE UTS VALUES AND FATIGUE PERFORMANCE PROVIDED BY ANCHORS REPAIR
- REDUCE TENDENCY OF GAP FORMATION BETWEEN TENDON AND BONE
- INCREASE THE HEMATIC SUPPLY TRHOUGH THE TUNNELS AND BY THE DECORTICATION OF THE FOOT PRINT (TRENCH)
- INCREASE FOOT PRINT COVERAGE
- REDUCE STRESS SPIKES
- ELIMINATE HARDWARE IN THE FOOT PRINT
- IMPROVE THE TUNNELS PERFORMANCE AVOIDING THE TUNNEL FAILURE
- VERSATILE APPROACH THAT PERMITS A GOOD PERFORMANCE EVEN WITH OSTEOPENIC BONE, WITH SUB CONDRAL CYSTS, IMPROVE REVISION REPAIR AND ELIMINATE INTRA-OPERATIVE PUL OUT
- EASY AND REPRODUCIBILE APPROACH



#### OUR EXPERIENCE WITH SHARC-FT Main features

- Sutures isolated by bone that act vertically
- •
- Performance independent by bone quality
- Minimum bone bridge 15 mm
- Absence of hardware in the foot print area; possibility of heavily decorticate foot print
- Eliminated risk of intra articular migration





Musculoskelet Surg (2013) 97 (Suppl 1):S57-S61 DOI 10.1007/s12306-013-0254-3

ORIGINAL ARTICLE

The rotator cuff tear repair with a new arthroscopic transosseous system: the Sharc-FT<sup>®</sup>

P. Baudi · E. Rasia Dani · G. Campochiaro · M. Rebuzzi · F. Serafini · F. Catani





## 34 patients at 18 Months ...

- from September 2010 to June 2013: 98 devices implanted (45 M 53 F)
- average age: 63,6 ys (41 77)
- Lesion type: 1-3 cm, SVSP + STSP
- 30 patients with an average follow up of 24 months (20 26)
- clinical outcome: Constant-Murley score pre-op at 3,6,12 and 24 months
- imaging evaluation
  - Rx post-op and after 1 year
  - RM at 6 months
- operative technique:
  - 1 Sharc-FT<sup>®</sup> loaded with 3 medial sutures
  - Compasso<sup>®</sup>
  - suture configurations SR /SB

## RESULTS



Constant score	AVE.	Min	Max
pre-op.	24.5	16	68
3 M	63.1	44	82
6 M	83.2	47	90
12 M	86.9	48	90
24 M	87.0	56	90

• RM at 6 months:

- no device migration
- ✤ no non-healing
- no re-tear

#### Complications at 24 M 2 adhesive capsulitis 1 clinical failure

Rx at 1 year:
\* no device migration

**Re-tear suspected** 





Versatility of the approach







Versatility of the approach







Versatility of the approach







Versatility of the approach





## Versatility of the approach









Versatility of the approach







Versatility of the approach





## Versatility of the approach







#### Versatility of the approach













## Greater tuberosity fracture





Greater tuberosity fracture



#### Greater tuberosity fracture


















































































#### Gap formation independend by bone quality ۲



Load condition

#### 500 cycles 10N-100N 0,2Hz

#### Accepted Manuscript

Gap formation in a transosseous rotator cuff repair as a function of bone quality

M. Mantovani, P. Baudi, P. Paladini, A. Pellegrini, M.A. Verdano, G. Porcellini, F. Catani

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DOI:	doi: 10.1016/j.clinbiomech.2014.01.00
Reference:	JCLB 3749

Clinical Biomechanics To appear in: 26 August 2013 Received date: Accepted date: 22 January 2014





## **CONCLUSION: OUR EXPERIENCE**

THIS NEW APPROACH PERMITS TO CREATE A STABLE AND REPRODUCIBLE CONSTRUCT THAT MAXIMIZE THE FOOT PRINT COVERAGE AND OPTIMIZE THE CONTACT PRESSURE

FLEXIBLE APPROACH CAN PERMIT SEVERAL DIFFERENT CONFIGURATIONS BASED ON THE SINGLE CLINICAL EXPERIENCE; CAN BE CONSIDERED A SUTURES PLATFORM AND MULTIPLE SUTURES CAN BE LOADED AS NEEDED

THE CLASSICAL TRANSOSSEOUS APPROACH CAN BE EASILY REPLICATED IN AN ARTHROSCOPIC FASHION OVERTAKING THE PREVIOUS LIMITATIONS OF THE TRANSOSSEOUS REPAIR



## **CONCLUSION: OUR EXPERIENCE**

APPROACH PARTICULARLY ADAPT TO LESIONE GREATER THAN 2 CM, IN CASE OF POOR BONE QUALITY, WHEN A REVISION IS NEEDED

### IT CAN BE USED EFFECTIVELY IN TUBEROSITIES FRACTURES IN THE OPEN SUBSCAP REPAIR

## **1 IMPLANT IS EQUIVALENT TO 4 ANCHORS**







Carpi, 17/07/2013



# Biomechanical rationale:

• Sutures isolated from bone (bone cut eliminated)





# Biomechanical rationale:

• Construct independent by bone quality



MEDICAL DEVI



The gap measurement in a dynamic test is not only reduced compared to a transosseous approach but it has a lower variability changing the bone quality.

Loading condition: 500 cycles 10N-100N 0,2Hz

NCS Lab Srl. Via Pola Esterna 4/12 - 41012 Carpi (MO) Italy



• High static and dynamic performance (gap formation is very low compared to currently used techniques)





• High static and dynamic performance (gap formation is very low compared to currently used techniques)



Sharc-ft s	Sharc-ft samples		mm samples
Mean (N)	STD Dev. (N)	Mean (N)	STD Dev. (N)
315.8	11.5	215.5	16.0



NCS Lab Srl. Via Pola Esterna 4/12 - 41012 Carpi (MO) Italy



 High static and dynamic performance (gap formation is very low compared to currently used techniques)





Sharc-ft			
Damage [mm]	Mean n° of cycles	Standard deviation	
3	411.6	334.1	
5	1284.0	989.2	
10	2938.6	1940.2	

Anchor			
Damage [mm]	Mean n° of cycles	Standard deviation	
3	212.0	154.8	
5	420.3	444.1	
10	1183.3	1119.4	

Gap reduction in a dynamic set up compared to double row techniques (massive lesion).

NCS Lab Srl. Via Pola Esterna 4/12 - 41012 Carpi (MO) Italy



Force

DR repair (4 anchors)





Larger coverage of the foot print area and better pressure distribution



New FEA model to predict repair efficacy. (paper submitted)



Repair method	Repair Area (mm²)	Contact area with a positive pressure (mm <sup>2</sup> )
Transosseous with a device in the tunnel	125	45,4
Transosseous Equivalent (4 anchors, 2 screwed and 2 impacted laterally)	103	42
Single Row	35	15,9
Double Row	87	26,8

Qualitative maps of the sliding contacts; the orange color represents the area in contact with a positive applied pressure. In yellow the frees surfaces while in blue the absence of contact at all. In the left up corner the SR, in the right up corner the DR, in the lower left side the TE and in the lower right corner the evolution of the transosseous approach.



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NCS Lab Srl. Via Pola Esterna 4/12 - 41012 Carpi (MO) Italy

# Change the rules!

Sharc-FT® NCS Lab Srl. Via Pola Esterna 4/12 - 41012 Carpi (MO) Italy



#### Arthroscopic trans-osseous rotator cuff repair

#### Claudio Chillemi<sup>1</sup> Matteo Mantovani<sup>2</sup>

<sup>1</sup> Department of Orthopaedic Surgery, Istituto Chirurgico Ortopedico Traumatologico ICOT, Latina, Italy

<sup>2</sup> NCS Lab, Srl, Carpi, Italy

#### Corresponding author:

Claudio Chillemi Department of Orthopaedic Surgery, Istituto Chirurgico Ortopedico Traumatologico ICOT Via Franco Faggiana 1668 04100 latina, Italy E-mail: c\_chillemi@libero.it

#### Summary

Background: Mechanical factors are at the basis of any tendon healing process, being pressure an aspect able to positively influence it. For this reason transosseous rotator cuff repair represents the gold standard procedure for patients affected by a cuff tear, maximizing the tendon footprint contact area and reducing motion at the tendon to bone interface.

Methods: The authors present an all arthroscopic suture bridge-like transosseous repair with the preparation of a single transosseous tunnel performed thanks to a precise dedicated instrument (Compasso®) and one implant (Elite-SPK®) with the use of only 3 suture wires. In addition this technique permits to accurately prepare the bony side of the lesion without any risk or complication, such as anchor pull-out and greater tuberosity bone osteolysis.

*Conclusions:* However, even if this technique seems less demanding, the arthroscopic transosseous repair is still an advanced procedure, and should be performed only by well prepared arthroscopic shoulder surgeons. Level of evidence: V.

KEY WORDS: arthroscopy, repair, rotator cuff, shoulder, tear, tendon, trans-osseous technique.

#### Introduction

Arthroscopic rotator cuff (RC) repair techniques have

evolved significantly during the last decades<sup>1</sup>. However the occurrence of re-tear<sup>2</sup> or non-healing<sup>3</sup> is still high, and numerous variables are to be considered in order to make an adequate surgical choice<sup>4</sup>. Different kinds of suture configurations were developed in the last years trying to optimize RC tendon healing biology at the repaired site<sup>5-7</sup>. At first, the double-row techniques added a row of suture anchors fixation lateral to the conventionally placed medial row that had represented the standard fixation strategy for arthroscopic RC repairs<sup>8</sup>. Later, in an effort to combine the stronger biomechanical repair of the double-row configuration with the increased tendon-bone interface pressure benefits, the transosseous-equivalent (TOE) suture bridge repair was developed<sup>9,10</sup>.

This technique preserves the suture limbs of the medial row bridging them over the tendon's native insertion with fixation in the lateral humeral cortex providing also an optimal load sharing. Several studies reported the biomechanical superiority of TOE RC repair over the standard double row and single-row repair techniques due to the ability to provide compression through the footprint by increasing the contact area. This is achieved by connecting the medial and lateral rows, thus exerting compression throughout the repair, instead of only at the anchor insertion points<sup>2,9-11</sup>.

However, failures at the medial row with a well-attached tendon on the great tuberosity have been reported with the TOE technique<sup>12,13</sup>.

Moreover other anchor-related complications (pull out in presence of poor bone stock, greater tuberosity bone osteolysis, difficult revision, increased cost) called into question the use of anchor fixation for RC repair<sup>14,15</sup>.

For these reasons, the best arthroscopic technique has not yet been established and open transosseous (TO) RC repair is to be considered the gold standard procedure<sup>15</sup>. As recently established, mechanical factors are at the basis of any healing process, being pressure an aspect able to positively influence the healing process<sup>16</sup>. The TO technique permits to maximize the tendon footprint contact area<sup>2</sup> and to reduce motion at the tendon to bone interface<sup>17</sup>. In addition to this mechanical aspect, TO technique permits to accurately prepare the bony side of the lesion without any risk or complication, such as anchor pull-out and greater tuberosity bone osteolysis<sup>15,18</sup>.

In an attempt to overcome the limitations of anchor repair, arthroscopic TO anchorless RC repair techniques have recently been developed<sup>6,14,15,17-19</sup> (Tab. I).

Authors	Year	N° of tunnel	N° of sutures	Instrumentation
H Frick <sup>11</sup>	2010	1 or more	1-3 for each tunnel	Bone needle
R Garofalo <sup>12</sup>	2012	1 or more	2-3 for each tunnel	ArthroTunneler
S Kuroda <sup>17</sup>	2013	3	5	Drill guide + 3 k-wires
EM Black3	2015	2	6	ArthroTunneler
M Aramberri-Gutierrez <sup>1</sup>	2015	1(medial calcar)	2(1 soft anchor)	ACL-guide
BA Flanagin <sup>9</sup>	2016	1 or 2	3 or 6	ArthroTunneler

Table I. Arthroscopic trans-osseous rotator cuff repair techniques recently published for the treatment of full-thickness tendon tear.

In this paper a novel and reproducible all-arthroscopic TO anchorless technique that replicates the TOE suture bridge repair is reported. This novel technique avoids all the disadvantages related to anchor fixation. The principle is to combine the double-row suture bridge fixation with the classic TO approach of suture fixation as performed in the open rotator cuff repair.

#### Surgical technique

The procedure can be performed depending on anesthesiologist preference under general anesthesia or interscalene brachial plexus block or combined, and in beach-chair position or lateral decubitus according to surgeon request.

The authors suggest using a 3 portals surgical technique: standard posterior (for the scope), lateral and antero-superior (working) portals. Once the reparability of the RC lesion is assessed we advise firstly to treat possible associated pathology (LHB tenotomy/ tenodesis, subscapularis repair).

After tendon and bone preparation for suture (respectively cutting and refreshing the torn tendinous edge and wide surface decortication of the footprint providing maximum spongy bone) is possible to prepare the TO tunnel. A dedicated instrument, named Compasso® (NCS Lab s.r.l. - Medical Devices Factory, Italy) was developed with the aim to simplify and accelerate the operative procedures avoiding pitfalls or damages to soft tissues.

Place the Compasso® (Fig. 1) parallel to the coronal plane with the tip of the proximal punch (part 1 with lanceolate tip) corresponding to the desired exit point of the transosseous tunnel you wish to perform. The angle of insertion of the proximal punch should be between 30° and 45°, depending on the protrusion of the acromion. Use the hammer to sink the proximal punch in the humeral head until it stops and reach the



Figure 1. Positioning of the guide (Compasso®) to perform the transosseous tunnel: the tip of the proximal punch (1) corresponds to the desired exit point of the tunnel, while the pin of the distal punch (2) reaches the lateral cortex of humerus. A monofilament shuttle suture is loaded distally and captured by a suture locker proximally. cannula enlargement (mechanical stop). Insert the distal punch (2) inside the distal cannula, then assemble these parts on the main body of Compasso® until the pin of the punch reaches the lateral cortex of humerus. For a correct insertion align the laser marks of cannula and main body. Unscrew the locking ring on the main frame to set the angle between the distal and the proximal cannula so as to place the pin of the distal punch approximately at 12-15 mm from the edge of the greater tuberosity, then tighten the locking ring firmly again, once in the desired optimal position. The cranial-caudal angle can be defined until cannula 2 is inserted into the bone. The anterior-posterior position of the instrument, instead, must be defined before the subcutaneous insertion. Hammer the distal punch (2) to pass the lateral cortex of the humerus for some millimeters, to stabilize the device, then lift the proximal loading punch (1) until the laser mark on it becomes visible. Hammer the distal cannula (2) till it comes in contact with the main body of Compasso®. Remove the distal inner punch from its cannula. Load a monofilament shuttle suture (PDS size USP 1 or 2) through the distal cannula until it stops. Insert the suture locker (part 1 with rounded tip) through the proximal cannula (1), then tighten it to steadily capture the shuttle suture.

Check the optimal engaging of the shuttle suture by pulling the external limb. Remove the distal cannula

from the main body of Compasso®. Pull the Compasso® out from the medial access of the transosseous tunnel by dragging with it the shuttle suture. This shuttle could drag the suture wires connected to the front part of the implant, the Elite-SPK® (NCS Lab s.r.l. - Medical Devices Factory, Italy) (Fig. 2a). It is an implant made of PEEK containing two separated eyelets: a rear one, that remains externally on the lateral cortex of the humerus, and a front, smaller one through which sutures are initially loaded. Along the body of the device several stabilising flaps are attached to the main body which, in combination with the wide contact surface beneath the head of the implant, have the function of providing an optimal primary stability (Fig. 2b).

Depending on the tear size a different numbers of sutures can be passed. We recommend to shuttle 3 sutures (of different colours). Before this step to avoid any sliding of the wires, we perform 2 simple knots for each suture, in the front part of the implant (Fig. 2b). All the six stitches are then passed through the cuff (Fig. 3) with different devices according to surgeon preference, from posterior to anterior, and different kinds of suture configurations can be created. The senior surgeon (CC) in collaboration with the engineer (MM) developed the configuration below reported and named 2MC (double MC). Schematically we refer to limb 1 as the most anterior, going to limb





Figure 2 a-c. **a)** The shuttle suture drag the suture wires connected to the front part of the implant, the Elite-SPK®.

**b)** The Elite SPK® is an implant made of peek containing two separated eyelets: a rear one, that remains externally on the lateral cortex of the humerus, and a front, smaller one through which sutures (in number of 3, of different colours) are initially loaded. To avoid any sliding of the wires, it is better to perform 2 simple knots for each suture. Along the body of the device several stabilising flaps are attached to the main body which, in combination with the wide contact surface beneath the head of the implant, have the function of providing an optimal primary stability.

**c)** Arthroscopic view (with the scope posterior). Insertion of the Elite SPK® into the TO tunnel through the hole yet performed into the lateral cortex of the humerus. Note the stabilising flaps.



Figure 3 a, b. **a)** All the six stitches are then passed through the cuff (with different devices according to surgeon preference) from posterior to anterior. **b)** Arthroscopic view (with the scope posterior). Note the six stitches passed through the cuff, and all retrieved through the lateral portal.

6 for the most posterior. We firstly close the limb 2 with 3 (*suture 1*), and later the limb 4 with 5 (*suture 2*) leaving free the limbs 1 and 6 (Fig. 4). After cutting respectively one of the end of suture 1 and 2, we shuttle from anterior to posterior in the external eyelet of the Elite SPK® the limb 1 and the remaining end of suture 1 (Fig. 5). At this point, in order to achieve a repair in closed loop configuration, we tie the knot (laterally) between the limbs 1 and 6, and the remaining limb of suture 1 and 2 (Fig. 6). This represents a very tight and stable repair configuration that permits to completely cover the greater tuberosity. Surgery ends with subacromial decompression if necessary.

#### Discussion

A larger and more stable tendon-to-bone contact interface during the early phase of the healing process is nowadays a worldwide accepted concept<sup>16,20,21</sup>, so that different techniques have been developed to obtain a more anatomic configuration of the RC repair on the footprint providing a better environment for tendon healing.

During the last years the demonstration that the suture tension for any TO technique provides a more direct tendon-to-bone compression vector and a larger repair site contact area when compared to the suture



Figure 4 a, b. *2MC suture configuration*. **a)** Schematically we refer to limb 1 as the most anterior, going to limb 6 for the most posterior. Firstly close the limb 2 with 3 (*suture 1*), and later the limb 4 with 5 (*suture 2*) leaving free the limbs 1 and 6. **b**) Arthroscopic view (with the scope posterior). The surgeon firstly ties the knot between the limb 2 with 3.



Figure 5. *2MC suture configuration*. After cutting respectively one of the end of suture 1 and 2, shuttle from anterior to posterior in the external eyelet of the Elite SPK® the limb 1 and the remaining end of suture 1.



Figure 6. *2MC suture configuration*. At this point, in order to achieve a repair in closed loop configuration, tie the knot (laterally) between the limbs 1 and 6, and the remaining limb of suture 1 and 2.

anchor technique has lead to the introduction of arthroscopic TO RC repair techniques<sup>9,10</sup>.

Several papers in literature deal with this topic, but the general impression is that the arthroscopic TO technique are still technically demanding and with a lot of uncontrollable variables. Numerous dedicated instruments have been employed to create the TO tunnels into the greater tuberosity from the ACL tibial guide to different kinds of needle or tunneler devices<sup>15,22-24</sup>. However, all the arthroscopic TO techniques described until now are complex procedures that requires several surgical steps, the creation of 2 or more TO tunnels and the use of many sutures making these procedures very difficult to reproduce and standardize<sup>6,14,15,18,19</sup>.

In addition some complications such as needle breakage, neurological damage or greater tuberosity fracture can be encountered. Moreover, depending on the tear size, in order to equally distribute the forces on the tendon and to prevent the bone cutting phenomenon, it is mandatory to create more than 1 TO tunnel and use at least 2 or 3 sutures in each tunnel with the risk of suture twist and an increase of the surgical time required.

Using a dedicated and very precise instrument (Compasso®) to create a single TO tunnel and a single implant (Elite-SPK®) with 3 sutures the current technique permits to obtain a wide contact surface between the tendon and the bone with a biomechanical effectiveness comparable with the open TO technique while reducing the complexity and difficulty that is usually encountered with other arthroscopic TO techniques.

The peculiar shape of the implant and its features make it a suture platform that can also be used on very fragile bone tissue without the problem of migration and pull out, providing a reliable fixation. Two of the major problems previously described with arthroscopic TO techniques have been suture abrasion against the bone tunnel which can result in suture rupture, and bone cut in presence of poor bone (cheese cut effect) with damage of the remaining bone integrity and weakening of the tuberosity. With the use of Elite-SPK®, as there is no sliding of the suture wires into the TO tunnel, the risk of suture cut and bone damage is significantly reduced. In addition, while the other arthroscopic TO techniques generate a tendon compression vector directed laterally and tangential to the bone, the tendon compression vector provided by the Elite-SPK® is perpendicular to the footprint resulting in a maximization of the contact area (with an optimal pressure distribution) while reducing sutures-bone tunnel impingement and thus suture abrasion and bone damage. For this reason the Elite-SPK® seems particularly convenient in presence of osteoporotic bone or intraosseous cysts where usually suture anchors fail.

The 2 MC suture configuration allow the surgeon to build a suture-bridge like construct that increases the contact area and optimizes the compression of the tendon on the footprint. In particular, the 2 central double-row sutures provide stability and compression while the most anterior and the most posterior wires once tied together on the lateral aspect of the great tuberosity result in an enveloping effect on the tendon providing a complete coverage of the footprint.

The 2 simple knots for each suture tied in the front part of the implant are essential to avoid any sliding up of the limbs when tying the knot between limb 2 and 3 and limb 4 and 5, permitting a really good contact tendon to bone. Moreover, it is known that the three sutures passed through the TO tunnel share the load on the tendon resulting in a reduction of the local stress spikes at the tendon interface<sup>25</sup>.

#### Conclusion

The current technique allows to perform an all arthroscopic suture bridge-like TO repair with the preparation of a single TO tunnel performed thanks to a precise dedicated instrument (Compasso®) and one im-

plant (Elite-SPK®) with the use of only 3 suture wires. However, even if this technique is less demanding, the arthroscopic TO repair is still an advanced procedure, and should be performed only by well prepared arthroscopic shoulder surgeons.

#### Ethic

The Authors declare that this research was conducted following basic ethical aspects and international standards as required by the journal and recently updated in<sup>26</sup>.

#### **Conflict of Interest**

Claudio Chillemi declares that he has no conflict of interest. Matteo Mantovani designed and manufactured the Compasso® + Elite-SPK®.

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To all the staff of the Operating Theatre of ICOT - Latina and of the Laboratory of NCS – Carpi.

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**TECHNICAL NOTE • SHOULDER - ARTRHOSCOPY** 

## Arthroscopic transosseous rotator cuff repair: the eight-shape technique

Claudio Chillemi<sup>1</sup> · Matteo Mantovani<sup>2</sup> · Marcello Osimani<sup>3</sup> · Alessandro Castagna<sup>4</sup>

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Abstract All-arthroscopic anchorless transosseous suture techniques combine the advantages of the open transosseous repair with the benefits of arthroscopic technique. However, all the techniques described until now are very complex, difficult to reproduce and associated with an increased surgical time. The authors developed a novel allarthroscopic anchorless transosseous suture technique easy to perform and to reproduce. This procedure maximizes the tendon-footprint contact area obtaining both medial and lateral fixation without using any device, employing only 1 suture tape so to avoiding the risk of suture twist. The preparation of two transosseous tunnels is very easily and safely performed thanks to a dedicated instrument. The procedure is described in details. Moreover, the preliminary favorable results after a minimum follow-up of 12 months are reported.

**Keywords** Rotator cuff · Tendon · Tear · Repair · Transosseous technique · Arthroscopy

Claudio Chillemi c\_chillemi@libero.it

- <sup>1</sup> Department of Orthopaedic Surgery, Istituto Chirurgico Ortopedico Traumatologico (ICOT), Via F. Faggiana, 1668, Latina, Italy
- <sup>2</sup> NCS Lab Srl, Carpi, Italy
- <sup>3</sup> Department of Radiological Sciences, University of Rome "Sapienza", ICOT, Latina, Italy
- <sup>4</sup> Shoulder Unit, IRCCS Humanitas Institute, Milan, Italy

#### Introduction

For many years, open repair with transosseous (TO) sutures was considered the gold standard treatment for full-thickness rotator cuff tears (RCT). The advent of arthroscopy has revolutionized rotator cuff surgery, and nowadays, arthroscopic rotator cuff repair is becoming the new gold standard as it is less invasive and preserves the deltoid muscle [1, 2]. However, despite the significant improvement of fixation devices (the trend spans from screwed to beaten up to the latest all suture anchors with a continuous material evolution-from titanium, resorbable, peek and UHMWPE) and surgical techniques (single row, double row, suture bridge) that occurred in the last years, nonhealing or re-tear rate after arthroscopic rotator cuff repair is still high and it varies between 39 and 94% depending on the number of tendons involved, the patient's age and the tear size [3, 4]. Although there is no general consensus as to the causes of non-healing, taking into account that biological factors are likely to play a major role, a potential limitation of the arthroscopic technique has been related to the use of suture anchors, particularly when used in a single-row configuration, which is not able to completely reproduce the bone-tendon footprint [5, 6].

Nevertheless, no final evidence of better clinical outcomes has been demonstrated between single- and doublerow repairs [7, 8] and re-tear after a double-row repair may lead to a medial failure whose management is complicated [9].

Furthermore, the use of anchors has been associated with several complications including anchor pullout in case of poor bone quality and greater tuberosity bone osteolysis [10]. In addition to that, suture anchors are expensive, particularly if used in a double-row or suture-bridge configuration and may have limited efficacy in cases of



revision where multiple anchors have previously been implanted into the tuberosity footprint or in the presence of poor bone quality [11, 12]. In an attempt to overcome these limitations, all-arthroscopic anchorless TO suture repairs of the rotator cuff have recently been developed [9, 11-13]Several studies demonstrated that TO tunnels give excellent hold and that TO repairs are associated with a higher load to failure and yield less interference motion when compared to suture anchors [14, 15]. All-arthroscopic anchorless TO suture techniques combine the advantages of the open TO repair with the benefits of arthroscopic technique. However, all the techniques described until now are very complex, difficult to reproduce and associated with an increased surgical time. The authors developed a novel all-arthroscopic anchorless TO suture technique easy to perform and to reproduce. This procedure maximizes the tendon-footprint contact area obtaining both medial and lateral fixation without using any device. In the current technical note, the procedure is described in details and the preliminary results after a minimum follow-up of 12 months are reported.

#### Materials and methods

Between January 2014 and April 2015, 12 patients (8 males and 4 females, mean age 61.4 years  $\pm$  4) with a partial or full-thickness RCT underwent arthroscopic TO repair by the first author (CC) using the technique below described. Inclusion criteria were: partial or full-thickness RCT on the preoperative magnetic resonance imaging (MRI), no previous shoulder surgery, no previous shoulder injections, no previous shoulder infection. Patients with glenohumeral instability, arthritis and stiffness were excluded from the study. Nine patients presented a full-thickness RCT, while 3 patients had a partial articular-side lesion. Of the patients with a full-thickness RCT, 4 had a small lesion (C1 according to Snyder's classification [16], while 5 had a moderate/large lesion (C2-C3). All patients were followed up after a minimum of 12 months clinically by evaluation of the UCLA score and the visual analog scale for pain (VAS; 0 = no pain, 10 = maximum pain). The paired t test was used to determine whether there was a significant difference between preoperative and postoperative UCLA and VAS scores. A P value of less than 0.05 was considered to be statistically significant.

#### Surgical technique

The procedure can be performed depending on anesthesiologist preference under general anesthesia or interscalene cervical plexus block or combined, and either in beachchair or in lateral decubitus position according to surgeon request.

The authors suggest to use a 3-portal surgical technique: standard posterior (for the scope), lateral and antero-superior (working) portals. Once the reparability of the RCT is assessed is advisable firstly to treat possible associated pathology (long head of the biceps tenotomy/tenodesis, subscapularis repair).

After tendon and bone preparation for suture (respectively, cutting and refreshing the torn tendinous edge and wide surface decortication of the footprint providing maximum seal bone), it is possible to prepare the two TO tunnels required for this technique. A dedicated instrument was developed with the aim to simplify and accelerate the operative procedure avoiding pitfalls and damages to soft tissues.

Once located the lateral cortical entry point (approximatively at about 15–20 mm distally to the greater tuberosity), a 2-mm entrance hole is prepared anteriorly. The device, named Taylor Stitcher<sup>®</sup> (NCS Lab s.r.l.— Medical Devices Factory, Italy) (Fig. 1a), permits to perform the TO tunnel through the handle screwing that controls the advancement of a Superelastic Transosseus Needle<sup>®</sup> (STN). Thanks to its multiradius shape, led by the position limiter, the Taylor Stitcher<sup>®</sup> performs TO tunnels in the footprint area. Tunnels are 3 mm in diameter and present a smooth curved morphology. The shuttle wire is then passed in one single step with the STN (having an eyelet close to the tip) through the TO tunnel so that the suture wires can be dragged into it.

In case of moderate/large full-thickness RCT (C2-C3 Snyder classification), after the shuttle wire is passed through the TO tunnel, it is retrieved through the anterior portal and then passed through the medial portion of the tendon with different devices according to surgeon preference. The same procedure is repeated to prepare another TO tunnel posteriorly, leaving a minimum bone bridge of approximatively 10 mm between the 2 TO tunnels in AP direction (Fig. 1b). The two shuttle wires that have passed through the anterior and posterior TO tunnels and through the anterior and posterior aspects of the medial portion of the tendon are available and retrieved through the anterior portal (Fig. 2a). Each shuttle wire is then used to pass one extremity of a smooth suture tape (FiberTape, Arthrex, USA) through the tendon and through the TO tunnel so that one extremity is passed through the anterior aspect of the medial portion of the tendon and the anterior TO tunnel and the other one is passed through the posterior aspect of the medial portion of the tendon and the posterior TO tunnel (like a reverse "U") (Fig. 2b). Both extremities of the tape are then retrieved from the lateral cortical entry points of the tunnels through the lateral portal. Before knot tying, the pressure effect of the mattress suture onto the footprint with closure of RCT can be proved by pulling the suture


**Fig. 1 a** The Taylor Stitcher<sup>®</sup> permits to perform the TO tunnel through the handle screwing that controls the advancement of a Superelastic Transosseus Needle<sup>®</sup>. The shuttle wire is then passed in one single step with the STN (having an eyelet close to the tip) through the TO tunnel so that the suture wires can be dragged into it. **b** Once located the lateral cortical entry point (approximatively at about 15–20 mm distally to the greater tuberosity), a 2-mm entrance hole is prepared. Thanks to its multiradius shape, led by the position limiter, the Taylor Stitcher<sup>®</sup> performs TO tunnels in the footprint area. Tunnels are 3 mm in diameter and present a smooth curved morphology. The same procedure is repeated to prepare another TO tunnel posteriorly, leaving a minimum bone bridge of approximatively 10 mm between the 2 TO tunnels in AP direction

ends. The medial mattress suture is then completed performing an arthroscopic knot on the lateral cortex of the great tuberosity (Fig. 3). Sliding knots should be avoided because of the potential tissue damage resulting from the sawing motion of these knots. After tying the knot, the two extremities of the suture instead of being cut are then used to perform an additional passage through the lateral portion of the tendon in order to obtain a double-row-like configuration (eight shape). Using the device that best works for the operating surgeon, the extremities are passed through the lateral portion of the tendon slightly anterior and posterior to the medial suture (Fig. 4a). The figure of eight is completed performing a second arthroscopic knot on the tendon so to obtain a trapezoidal double mattress suture configuration. The extremities of the suture are then cut (Fig. 4b). Surgery ends with subacromial decompression if necessary.



Fig. 2 a The two shuttle wires that have passed through the anterior and posterior TO tunnels and through the anterior and posterior aspects of the medial portion of the tendon are available and retrieved through the anterior portal. **b** Each shuttle wire is then used to pass one extremity of a smooth suture tape through the tendon and through the TO tunnel so that one extremity is passed through the anterior aspect of the medial portion of the tendon and the anterior TO tunnel and the other one is passed through the posterior aspect of the medial portion of the tendon and the posterior TO tunnel (like a reverse "U")



Fig. 3 Both extremities of the tape are then retrieved from the lateral cortical entry points of the tunnels through the lateral portal. The medial mattress suture is then completed performing an arthroscopic knot tied on the lateral cortex of the great tuberosity



Fig. 4 a After tying the knot, the two extremities of the suture instead of being cut are then used to perform an additional passage through the lateral portion of the tendon in order to obtain a double-row-like configuration (eight shape). The extremities are passed through the lateral portion of the tendon slightly anterior and posterior to the medial suture. **b** The figure of eight is completed performing a second arthroscopic knot on the tendon so to obtain a trapezoidal double mattress suture configuration

In case of *small full-thickness RCT* (C1 Snyder classification), the shuttle wire is directly passed with the STN through the TO tunnel and through the medial portion of the tendon in only 1 single step (transtendon technique). The procedure then continues as previously described.

In case of *partial RCT*, the shuttle wire is passed using the same transtendon technique. However, only one single transosseous mattress suture is performed on the lateral cortex of the great tuberosity. After tying the knot, the two extremities of the suture are cut without performing the additional passage through the tendon necessary to complete the eight-shape configuration.

#### **Preliminary results**

No intraoperative or postoperative complications were reported. The mean UCLA score significantly improved from 14.6 preoperatively to 32.2 points 12 months after surgery (P < 0.01), while the VAS score significantly improved from 8.3 to 2.1 (P < 0.01). No difference in clinical outcome was found between patients with partialthickness and patients with full-thickness RCT and between patients with small and patients with moderate/ large full-thickness RCT.

#### Discussion

Arthroscopic suture-anchor repair is the most widely used technique for treating RCT. However, in elderly patients anchor fixation can be a concern because of the poor bone quality of the greater tuberosity [13]. Moreover, other anchor-related shortcomings, such as difficulty with revision surgery because of the presence of anchors in the greater tuberosity, anchor dislocation and knot impingement, call into question the use of suture anchors in RCT repair [9]. Consequently, in the last few years several arthroscopic anchorless TO techniques have been described with the objective of avoiding the potential weaknesses of anchor fixation and also to provide significant cost savings for a procedure that has become quite expensive, particularly with the use of multiple suture anchors in various configurations [9, 11–13].

However, all the anchorless TO techniques previously described are complex to reproduce and standardize as they involve many surgical steps, the need of fixation devices and cannulas to manage a high number of suture wires so that particular care must be taken to ensure that the sutures have no twists and are not wrapped around one another, which is very time-consuming.

In addition to the significant prolongation of the surgical time, complications related to the instrumentation used (such as needle breakage) were also reported [6].

These techniques seem to be challenging for the majority of arthroscopic surgeons, and because of that they are also called "high demanding" techniques.

The eight-shape technique maximizes the biomechanical advantage of double-row repair using medial and lateral fixation to compress the rotator cuff over its natural footprint without the need for suture anchors or any fixation device. It is economic and easy to perform and to reproduce as it requires few surgical passages and only 1 tape suture that is used to obtain a trapezoidal double-row-like configuration. Moreover, while the other techniques can be used almost exclusively for large RCT, our technique can be performed for all types of RCT.

One of the major problems previously described with the TO technique has been suture cut through the bone tunnel wall or suture abrasion against the bone [17]. This is generally due to a substantial sharp angulated shape of the bone tunnels. With the eight-shape technique, bone tunnels present a curved trajectory without any angulation that allows an uniform contact between suture and bone. In addition, the particular configuration of our suture allows to share the load on the tendon and thus reduces the local stress at the bone interface.

The choice of the suture plays a key role in determining the strength of fixation, particularly in TO suture [17]. Although polyblend tape has comparable biomechanical performance when compared to the polyblend classic suture, it seems to provide a significant increase in tendonto-bone contact while offering a significantly lower and more equally distributed level of pressure [18]. The lower, more uniformly distributed level of compression may potentially reduce vascular restriction at the level of the repaired tendon and thus promote tendon healing [19].

The current technique is also convenient in the management of partial-thickness RCT allowing to perform a TO transtendon repair without touching the original intact side of the tendon. To our knowledge, there is only another arthroscopic TO transtendon technique for partial RCT described by Tauber et al. [20]. In that technique, a curved, sharp-cut, cannulated needle is introduced at the anterolateral edge of the acromion. As admitted by the authors, the learning curve of this technique is demanding, due to the requirement of experienced handling of the curved needle [20]. Moreover, buckling and breaking of the curved needle during entry into the greater tuberosity as well as fracture of the tip of the greater tuberosity were reported [20].

In our technique, the use of the Taylor Stitcher eliminates all these possible complications. The entry point is on the lateral cortex of the humerus, avoiding any conflicts with the acromion.

In addition, the TO tunnels are created in a smooth and gradual manner avoiding any risk of fracture.

In conclusion, the eight-shape technique presents several advantages over the published techniques. As it does not require any fixation device or cannula, and only 1 suture tape is used avoiding the risk of suture twist, the operating time is decreased. Furthermore, the preparation of the two TO tunnels, generally the most complex part of every TO technique, is very easily and safely performed thanks to the Taylor Stitcher. All of these features allow the eight-shape technique to be more cost-effective [10] and easily reproducible by any arthroscopic surgeon compared with the current published TO techniques [21].

#### Compliance with ethical standards

**Conflict of interest** Claudio Chillemi declares that he has no conflict of interest. Matteo Mantovani designed and manufactured the Taylor Stitcher<sup>®</sup> + Superelastic Transosseus Needle<sup>®</sup>. Marcello Osimani declares that he has no conflict of interest. Alessandro Castagna declares that he has no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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#### NCS Lab s.r.l. Via Pola esterna 4/12 - 41012 Carpi (MO) - Italy Tel./Fax +39 059 669813 - info@ncs-lab.com - VAT No. IT02550041202





		Design of the	Publication	Key Points
		Study/ Topic		
Pre-clinical Publication	1	Comparison between pure transoseous (Arthrotuneler) Vs augmented tranosseous (Sharc- Elite) in different sawbones densities	Gap formation in a atransosseous rotator cuff repair as a function of bone quality, Mantovani, Baudi, Paladini, Pellegrini, Verdano, Porcellini, Catani – 2014 Clinical Biomechanics Clinical Biomechanics Clinical Biomechanics Cap formation in a transosseous rotator cuff repair as a function of bone quality M. Martvani *, P. Badi *, P. Pladini *, A Peligrin <sup>4</sup> *, MA. Verdano <sup>4</sup> , G. Porcelini *, F. Catani * **********************************	<ul> <li>The use of Sharc/elite improves static and dynamic performance over pure tranosseous above all in severely osteoporotic bone</li> <li>Performance with sharc-elite in independent by bone quality</li> </ul>
	2	FEA simulation comparing single row, double row and transosseous equivalent	A 3D finite element model for geometrical and mechanical comparison of different supraspinatus repair techniques, Mantovani, Pellegrini, Garofalo, Baudi – 2015 Journal of Shoulder and Elbow Surgery	<ul> <li>Transosseous         <ul> <li>Transosseous</li> <li>equivalent shows</li> <li>the wider footprint</li> <li>coverage</li> <li>compared to single</li> <li>row and double</li> <li>row techniques</li> </ul> </li> <li>Stress in the cuff is         <ul> <li>reduced compared</li> <li>to single row</li> </ul> </li> </ul>
Clinical Publication/ case series	1	Case series (34 patients) with 1 year follow up. Augmented transosseous with Sharc- Article showing the use of Taylor stitcher in combination with Sharc/elite	The rotator cuff tear repair with a new arthroscopic transosseous system: the sharc-ft, Baudi, Rasia Dani, campochiaro, Rebuzzi, Serafini, Catani – 2013 Musculoskelet surgery         Macdedda Seg (2019 of Oper 1987-581 Determined to the Determined Sector Control of Competition (Sector Control Control of Competition)         Det of the Determined Sector Control of Competition (Sector Control of Cont	<ul> <li>Case series (34 patients average follow up 18 months) shows the technique is safe, produces excellent clinical outcome and it provides good fixation even when in presence of osteoporotic bone</li> <li>The taylor stitcher is used to do a single entry/double exit</li> </ul>
	3	Article showing the use of Compasso in combination with Elite	Technical Note         Arthroscopic Rotator Cuff Tear Transosseous Repair         System: The Sharc-FT Using the Taylor Stitcher         Andrea Pellegrini, M.D., Enricomaria Lunini, M.D., Manuela Rebuzzi, M.D.,         Michele Verdano, M.D., Paolo Baudi, M.D., and Francesco Ceccarelli, M.D.         Arthroscopic trans-osseous rotator cuff repair,         Chillemi, Mantovani – 2017 Muscles,         Ligaments and tendons Journal         Arthroscopic trans-osseous rotator cuff repair	construct in combination with au augmentation - Compass technique is shown in combination with Elite-spk
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#### NCS Lab s.r.l.

Via Pola esterna 4/12 - 41012 Carpi (MO) - Italy Tel./Fax +39 059 669813 - info@ncs-lab.com - VAT No. IT02550041202





	4	The taylor stitcher is used for a pure transosseous novel configuration repair technique: 8 shape	Arthroscopic transosseous rotator cuff repair: the eight shape technique, Chillemi, Mantovani, Osimani, Castagna Bur J Othog Surg Transatel DOT 1010704080017-1996-2 TECHNICAL NOTE • SHOULDER • ARTRHOSCOPY Arthroscopic transosseous rotator cuff repair: the eight-shape technique Claudio Chillemi <sup>1</sup> • Matteo Mantovani <sup>2</sup> • Marcello Osimani <sup>3</sup> • Alessandro Castagna <sup>4</sup>	-	8 shape is a novel double tunnels configuration showing a great potential for the combination of pure transosseous and tape Easy and cost effective technique
	5	27 patients with a 24 months follow up on large to massive lesions	AAOS 2016 presentation, Marchi, Petriccioli, Bertone SHARC-FT: outcomes January 2013 – December 2013 27 pts (14 females / 13 males) Involved Side: 16 right / 11 left (Dominant side 18 pts) Mean age 57,3 ys (range 42-74) Tear size (scor classification) • Large 10 (36%) • Massive 17 (64%)	-	All 27 patients showed excellent clinical outcome Despite the treated lesion sizes (where re-tear incidence can be high) no re-tear reported at 24 months
On going study	1	Level 1 clinical study comparing single row vs Augmented elite transosseous with a 2 years follow up: 18+18 patients.		-	Augmented transosseous vs 2- 3 anchors Preliminary data are excellent (excellent clinical result) Re-tear rate is very low
	2	Retrospective Level 3 study: 50 patients with a minimum follow up of 24 months. Ultrasound check at 2 years on all patients to look for re-tear rate.		-	50 patients having medium to massive lesions. Augmented transosseous repair (Elite) and minimum follow up of 24 months. Incidence of re- tear rate inferior to the published average
	3	Retrospective Level 3 study: 24 patients having cysts with a minimum follow up of 12 months. Post OP MRI.		-	This augmented transosseous is particularly effective in presence of cysts (where traditional device are unstable) and the clinical outcome is excellent. 24 patients show

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	4	Biomechanical set up on cadavers (9+9) augmented transosseous vs single row triple loaded anchors. Simulation of a revision case.	Biomechanical evaluation of an arthroscopic transosseous anchor as a revision option for rotator cuff repair, Dyma, Voss, Pauzenberger, Obopilwe, Mazzocca, Castagna, Edgar, 2016 Biomechanical evaluation of an arthroscopic transosseous anchor as a revision option for rotator cuff repair. Fait: Dyma, Andreas Voss, Leo Pauzenberger, Elifio Obopilwe, Augustus Mazzocca, Alessandro Castagna, Cory Edgar	good hea no re-tear - The au transossed approach (sharc/elit effective presence revision biomechan performar primary re - Footprint a comparab primary re - Heavy decorticat (favouring factors up recommen without repair inte - No further of the tu (as wit insertion additional hardware)	ling and gmented ous e) is very in of a (same nical nce as a pair) coverage le to a pair ion growth otake) is nded affecting grity damage uberosity h the of
Abstracts, Presentation & Posters	5	row technique and the other with pure transosseous by taylor stitcher) Clinical data collection: direct comparison between pure transosseous vs Sharc/elite augmented transosseous	<section-header><section-header><text><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></text></section-header></section-header>	<ul> <li>anchors transossed</li> <li>The augm reduces spread an outcome dispersed</li> <li>Healing p good in bo despite augmenta provides clinical performar</li> </ul>	vs pure bus) eentation data d clinical are less rocess is th group the tion a better
	2	Transosseous performances measured by changing synthetic bone quality	Gap formation in a transosseous rotator cuff repair as a function of bone quality, Mantovani, Baudi, Paladini, Pellegrini, Verdano, Porcellini, Catani – 2014	- The us Sharc/elite improves and performar pure tran above	se of static dynamic nce over nosseous all in





		Gap formation in a transosseous rotator cuff repair as a MCS	covoroly
		Function of bone quality         Construction           M. Mansael 4, Shade P. 2, Palade P. 2, Nation Mod. 5, Newton Mod. 5, New	osteoporotic bone
		<text><text><text><text></text></text></text></text>	<ul> <li>Performance with sharc-elite in independent by bone quality</li> </ul>
3	Rehabilitation with a transossoeus repair	Rehabilitation with a transosseous repair approach: common way or different protocol?, Pellegrini – 2017 Transosseous Academy 1st edition <b>CLINICA ORTOPEDICA</b> UNVERSITA' DEGLI STUDI DI PARMA <b>REHABILITATION WITH A TRANSOSSEOUS</b> <b>APPROACH: COMMON WAY OR DIFFERENT</b> <b>PROTOCOL</b> ? <b>WITTENDER</b> <b>WITTENDER</b> <b>WITTENDER</b> <b>WITTENDER</b> <b>WITTENDER</b> <b>WITTENDER</b>	<ul> <li>Patients having augmented transosseous show a quicker recovery (early measurements)</li> <li>Specific rehab program can be conceived to speed up the recovery in the post op period</li> </ul>
4	Tips and tricks to be successful in transosseous	Learning curve: tips and tricks to be successful in transosseous technique, Edgar – 2017 Transosseous Academy 1 <sup>st</sup> edition Learning Curve: Tips and tricks to be successful in transosseous technique Cory Edgar M.D., Ph D. Assistant Professor Department of Orthopedic Surgery UConn Health Center Team Physician: UCon Athletics Connecticut College US Coast Guard Academy	- Importance of portals position
5	Speech about scientific rational beyond transossoeus	What is the scientific rational in transosseous approach?, Edgar – 2017 Transosseous Academy 1st edition         Academy 1st edition         What is the Scientific Rational in Transosseous Approach?         What is the Scientific Rational in Transosseous Approach?         Cory Edgar M.D., Ph D. Asistant Professor Department of Orthopedic Surgery UConn Health Center Team Physician: UCon Athletics Connecticut College US Coast Guard Academy	<ul> <li>Decortication is recommended and doen't affect reprit integrity favouring instead biological repair</li> <li>Excellent for revision (no further hardware in the tuberosity)</li> <li>Excellent to be revised (no hardware in the tuberosity so is like a primary repair)</li> </ul>





	Massive lesion on a 6 cadaver lab – live	Massive lesion in presence of a severely osteoporotic bone, Baudi – 2016 Valencia	<ul> <li>More biomechanical repair favoring wide coverage</li> <li>No risk of hardware migration</li> <li>Cost effective</li> <li>Excellent repair despite very poor</li> </ul>
	7 Mini open subscap on a cadaver lab – live session	Isolated subscap repair, Baudi – 2016 Valencia	- Excellent repair and good option in combination with prosthesis
8	8	The transosseous return, new potentiality in rotator cuff repair: biomechanical rational and clinical outcome.         Image: transosseous return, new potentiality in rotator cuff repair: biomechanical rational and clinical outcome         Image: transosseous return, new potentiality in rotator cuff repair: biomechanical rational and clinical outcome	transosseous pros: - mantain or improve the uts values and fatigue performance provided by anchors repair - reduce tendency of gap formation between tendon and bone - increase the hematic supply trhough the tunnels and by the decortication of the foot print (trench) - increase foot print coverage - reduce stress spikes - eliminate hardware in the foot print - improve the tunnels performance avoiding the tunnel failure - versatile approach that permits a good performance even with osteopenic bone, with sub condral cysts , improve revision repair and eliminate intra- operative pul out





			-	easy and reproducibile approach
			Good for: - -	subscap in miniopen greater tuberosity fracture smaller tuberosity fracture
9	40 patients case series	Sharc-FT rotator cuff repair for a new transosseous suture technique: 12 months of follow up, 32 <sup>nd</sup> AANA         Orthopacdic Department UNIVERSITY of MODENA (ITALY) UNIVERSITY of PARMA (ITALY) UNIVERSITY of PARMA (ITALY)         Sharc-FT ROTATOR CUFF REPAIR FOR A NEW TRANSOSSEOUS SUTURE TECHNIQUE: 12 MONTHS OF FOLLOW UP         Paolo Baudi Michele Verdano Gabriele Campachiaro Andrea Pellegrini Fabio Catani Francesco Ceccarelli         With the support of Sharc Italian Board: G. Porcellini, D. Petriccioli, R. Rotini, E. Gervasi, G. Milano	-	40 patients with massive lesions treated successfully with augmented transosseous
10	Indications and early use.	Double-row surgical technique in rotator cuff repair, 5 <sup>th</sup> SIA international UNIVERSITA DEGLI STUDI DI VERONA Clinica Ortopedica e Traumatologica Direttore: Prof. P.Bartolozzi Double-row surgical technologue in rotator cuff repair E. Vecchini – F. Perusi - P. Bartolozzi	-	Stable and effective with every bone condition
11	Biomechanic studies collection to support the relation between biomechanic and clinic	Biomechanical tests, reproducibility in laboratory of the different rotator cuff repair techniques, 2013 Mantovani	-	It has been proven higher stability may be associated with higher healing probability Transosseous not only provides a better pressun distribution combined with a larger coverage but preserve





		interface tendone-
		suture



Orthopaedic Department UNIVERSITY of MODENA(ITALY) UNIVERSITY of PARMA (ITALY)

#### SHARC-FT ROTATOR CUFF REPAIR FOR A NEW TRANSOSSEOUS SUTURE TECHNIQUE: 12 MONTHS OF FOLLOW UP



Paolo Baudi
Michele Verdano
Gabriele Campochiaro
Andrea Pellegrini
Fabio Catani
Francesco Ceccarelli

With the support of Sharc Italian Board: G. Porcellini, D. Petriccioli, R. Rotini, E. Gervasi, G. Milano

# My disclosure is in the Final Program Book and in the AANA database.

#### I have no potential conflicts with this presentation.



Paolo Baudi Michele Verdano Gabriele Campochiaro Andrea Pellegrini Fabio Catani Francesco Ceccarelli

- cuff tear is more common in patients with shoulder's pain (36%)
- asymptomatic ones (16,9%)
   prevalence of the complete tears in general population is estimated approximately of 20,7%
- more usual with the increasing of the age





Different devices for arthroscopic cuff repair in the hands of surgeons:

Anchors
Pushlock, versalock
Transosseous suture
SHARC-FT



### **Differences in these different devices?**

Biomechanichs
Tendon-bone contact
Tendon pressure distribution
Devices migration or pull-out





#### **TRANSOSSEOUS vs ANCHORS**



Functional suture, tendon-bone contact and tendon-bone contact pressure distribution

# Transosseous technique gives more compression



The device use a transosseous tunnel to avoid the direct contact between bone and sutures





## Various configurations compared in term of contact area





The transosseous approach with SHARC-FT is able to produce a foot print contact area comparable to suture bridge approach





## The device has a slotted body designed to manage one to four inner sutures



# Sharing the forces acting between tendon and sutures

## Tensioning of external sutures during adduction



#### SHARC -ft transosseus cuff repair EASY AND REPRODUCIBLE ARTHROSCOPIC TECHNIQUE



"Share ft

## **BACKGROUND: operative technique**



### **MATERIALS AND METHODS**

□ 40 patients with massive cuff tear **mean follow up 12 months (6-18) mean age 63,6 y (41-77) Costant score, X-ray and MRI** control at the time of follow-up



 All patients undergoes arthroscopic cuff repair with SHARC-FT device



All the patients were immobilized with a shoulder sling



Rehabilitation protocol Depressor humeral head Balancing external/internal rotator Balancing with the deltoid







#### **Costant-Murley Score**



■ pre-op ■ 3 months post op ■ 6 months post-op ■ 12 months post-op



#### **Post-op**











No screw interference on foot-print image ! 1 partial re- tear

### **DISCUSSION**





## Tensioning of internal sutures during abduction



## **CONCLUSION**

- Good functional outcome at 12 months of follow up
  No migration devices or other complications
  Easy and reproducible arthroscopic technique
  - technique

### **<u>REFERENCE</u>**

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With the support of Sharc Italian Board: G. Porcellini, D. Petriccioli, R. Rotini, E. Gervasi, G. Milano

# THANK YOU FOR YOUR ATTENTION

Corresponding author: E-mail: Andrea Pellegrini a.pellegrini@aol.com



# Learning Curve: Tips and tricks to be successful in transosseous technique

#### Cory Edgar M.D., Ph D.

Assistant Professor Department of Orthopedic Surgery UConn Health Center Team Physician: UConn Athletics Connecticut College US Coast Guard Academy




## Italian Learning Curve -







## Learning Curve – Patient Position



Use What You are comfortable with!

### **Beach Chair**

**Targeting Easier - Adduction** 

### Lateral Decubitus

Sub-deltoid Bursa Easier Exposed – Traction effect

### Adduction Ability for Targeting







## Learning Curve – Lateral Incision

Axillary Nerve – What is the Worry?

Distance from Acromion Avg 6cm or 2cm from edge of GT









## Learning Curve – Lateral Incision



### Axillary Nerve – What is the Worry?

J Bone Joint Surg Am. 2006 Nov;88(11):2395-9.

### Is there a safe area for the axillary nerve in the deltoid muscle? A cadaveric study.

Cetik O<sup>1</sup>, Uslu M, Acar HI, Comert A, Tekdemir I, Cift H.

Distance from Acromion Avg 6cm or 2cm from edge of GT

A Comparison of Risk Between the Lateral Decubitus and the Beach-Chair Position When Establishing an Anteroinferior Shoulder Portal: A Cadaveric Study

Pablo Eduardo Gelber, M.D., Francisco Reina, M.D., Ph.D., Enrique Caceres, M.D., Ph.D., and Juan Carlos Monllau, M.D., Ph.D.



Arthroscopy. 1997 Oct;13(5):600-5.

Morphology of the axillary nerve in an anteroinferior shoulder arthroscopy portal.

Nassar JA<sup>1</sup>, Wirth MA, Burkhart SS, Schenck RC Jr.



## Learning Curve – Lateral Incision

Axillary Nerve – What is the Worry?

Anatomic Risks of Shoulder Arthroscopy Portals: Anatomic Cadaveric Study of 12 Portals

Matthieu Meyer, M.D., Nicolas Graveleau, M.D., Philippe Hardy, M.D., and Philippe Landreau, M.D.





FIGURE 1. Dissection planning 1 (right shoulder from above) (A, "soft-point" portal; B, anterior central portal; C, 5 o'clock portal; D, Port of Wilmington; E, lateral posterior portal; F, superolateral portal).



FIGURE 2. Dissection planning 2 (right shoulder from above) (G, central posterior portal; H, anterior superior portal; I, anterior inferior portal; J, Neviaser portal; K, lateral anterior portal; L, transrotator cuff approach portal).

Anterolateral	(Elmann)
Anteroraterar	(Emaini)

Posterolateral (Elmann)

posterolateral corner of the acromion2 cm below the lateral edge of the acromion in the prolongation its anterior edge2 cm below the lateral edge of the acromion

in the prolongation its posterior edge

(right shoulder) Medially to the subacromial bursa

Medially to the subacromial bursa



Lateral Portals	Axillary Nerve
Superolateral	58 [49-70] (11)
Transrotator cuff	53 [33-64] (12)
Port of Wilmington	55 [42-64] (9)
Lateral anterior	70 [57-80] (11)
Lateral posterior	56 [41-67] (13)

## Learning Curve – Tunnel Targeting





USKIES

## Learning Curve – Clear the Soft Tissue



### Visualization is Key:

- Cannulas
- Blood Pressure Control
- Efficient Surgery







<u>Passing Suture</u> – Avoid PDS, #4 Fiberwire

### **Retrieval Portal**









### First Case -



## **Good Luck and Enjoy!!**









Taylor Stitcher



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### **Clinical Biomechanics**



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### Gap formation in a transosseous rotator cuff repair as a function of bone quality

#### M. Mantovani<sup>a</sup>, P. Baudi<sup>b</sup>, P. Paladini<sup>c</sup>, A. Pellegrini<sup>d,\*</sup>, M.A. Verdano<sup>d</sup>, G. Porcellini<sup>c</sup>, F. Catani<sup>b</sup>

<sup>a</sup> NCS Lab, Carpi, Italy

<sup>b</sup> Orthopedic and Traumatology Department, University of Modena, Modena, Italy

<sup>c</sup> Unit of Shoulder and Elbow Surgery, D. Cervesi Hospital, Cattolica, Italy

<sup>d</sup> Orthopedic and Traumatology Department, University of Parma, Parma, Italy

#### ARTICLE INFO

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#### ABSTRACT

*Background:* The transosseous approach has been well known for a long time as a valid repair approach. Over time, various criticisms have been raised over this technique principally classifiable in two main categories: technical difficulty and related reproducibility in an arthroscopic environment, and repair stability (in the suturebone contact area). About cyclic performance, several authors have conceived test setups with the aim of simulating a real environment in dynamic load conditions. The aim of this study was to monitor gap formation in a cyclic test setup.

*Methods*: The performance (measured as gap formation) has been monitored as a function of bone density to verify the effect of the latter. The test blocks have been shaped using sawbones® test bricks (Malmo, Sweden) of different densities, and the following values have been tested: 10, 15, 20, 30 and 40 pcf.

*Findings:* The comparison has been made between the two groups: traditional transosseous and new approach with an interposed device. Regarding the traditional transosseous approach in a 10-pcf environment, not even the first loading cycle was completed, the whole bone bridge was destroyed in the first loading ramp and no further loading capability was present in the repair. By increasing the block density, the surface damage in the suture-block contact decreased.

*Interpretation*: With this work, it has been demonstrated how the traditional transosseous approach is strongly influenced by the bone quality up to the point where, in certain conditions, a safe and reliable repair is not guaranteed.

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#### 1. Introduction

The transosseous approach has been well known for a long time as a valid repair approach (Apreleva et al., 2002; Tashjian et al., 2008).

Over time, various criticisms have been raised over this technique principally classifiable in two main categories: technical difficulty and related reproducibility in an arthroscopic environment, and repair stability (in the suture-bone contact area). From the clinical point of view, these aspects have a direct implication in the mechanical stability and, therefore, the successful treatment of rotator cuff tears (Baudi et al., 2013).

So far, the basic drivers for an optimal repair have already been identified, and still today, they represent the state of the art. Between these basic drivers, Burkhart et al. (1997) found an optimal cyclic resistance for the avoidance of an excess tension in the repair and the need to look for a more distal area to the proximal metaphysis. About cyclic performance, several authors have conceived test setups with the aim of simulating a real environment in dynamic load conditions (Barber and Drew, 2012; Barber et al., 2010; Baums et al., 2008, 2010a,b; Bisson and Manohar, 2009; Busfield et al., 2008; Cummins et al., 2005; Dierckman et al., 2012; Kim et al., 2006; Kummer et al., 2011; Lee et al., 2005; Ma et al., 2004; Mahar et al., 2007; Mazzocca et al., 2005, 2010; Meier and Meier, 2006; Mihata et al., 2011; Milano et al., 2008; Nelson et al., 2008; Özbaydar et al., 2008; Park et al., 2007, 2008; Petit et al., 2003; Smith et al., 2006; Spang et al., 2009; Tashjian et al., 2008; Tauber et al., 2011; Tocci et al., 2008; Zheng et al., 2008).

Although a significant discrepancy is evident in both the way measurements are done and the final results provided, gap formation during cyclic loading is a fundamental parameter to be controlled in order to improve the quality and efficacy of the repair (Dines et al., 2010).

From a literature survey, it is evident that there is an absence of a sufficiently shared test protocol that adopts an objective way to assess gap formation and how the test dynamics influence the final result. An accepted and shared evaluation method would permit to objectively know when the transosseous approach is a suitable solution and

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<sup>\*</sup> Corresponding author at: University of Parma, Via Gramsci 14, 43100, Parma, Italy. *E-mail address*: a.pellegrini@aol.com (A. Pellegrini).

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transform the approach into a less sensitive repair method to the test conditions.

The aim of this study was to monitor gap formation in a cyclic test setup as described below.

#### 2. Methods

Gap formation was defined as the extension of the separation between tendon and bone contact. The performance (measured as gap formation) has been monitored as a function of bone density to verify the effect of the latter.

The test blocks have been shaped by sawbones® test bricks (Malmo, Sweden), made of polyurethane foam. The international standard specifications from ASTM F1839 declare that the physical properties of this material are in the order of those reported for the human cancellous bone. In particular, related to our study, previous works in literature have also reported failure strength and elastic modulus consistent with the human glenoid bone (Virani et al., 2008).

Bricks of different densities value were tested: 10, 15, 20, 30 and 40 pcf (the grade designation refers to the nominal density of the foam, as indicated in ASTM F1839).

In order to avoid any fault in the gap formation measurement, we decided to eliminate the knot tension variable. For this reason, we conceived proper grip equipment to firmly hold the sutures and to avoid them from sliding and at the same time to permit the application of the same pre-tension load in all cases without introducing superficial damages. The vertical translation was impeded firmly by using an aluminum plate fixed on the superior surface of the brick. The adopted suture clamp is presented in Fig. 1a. The four closing screws have been closed to a constant torque of 12 Nm in all test runs to avoid strand slippage in pre-test constant conditions.

The loading conditions were as follows: oscillating sinusoidal waveform from a minimum of 10 N up to 100 N and a test frequency of 0.2 Hz. A pre-tension of 10 N was applied for 1 min before starting the dynamic test, and at 500 repetitions, the test was stopped.

In Fig. 1b, the clamping system mounted on the loading machine is shown. The actuator permits to assess the loading direction; a coaxial LVDT sensor (displacement range  $\pm$  100 mm) is embedded by factory and aligned with a hydraulic actuator (Italsigma srl, Forlì, Italy) and recorded the displacement during the whole test.

The initial displacement was zeroed after this pre-load, and the sampling frequency was 100 Hz. The test end was reached when one of these two events occurred: load cycle number 500 was reached or a displacement of the vertical actuator exceeded 10 mm (the first event to occur was recorded as the test's final goal). Various authors reported analogous test loading conditions in literature (Barber et al., 2010; Baums et al., 2008, 2010a; Burkhart et al., 1997; Lee et al., 2005; Mahar et al., 2007; Petit et al., 2003).

To reproduce the transosseous repair, two different approaches were used: the first is the traditional transosseous method while the second made use of a new device named Sharc-Ft® (NCS lab srl, Modena, Italy) and a correspondent instrument named "compasso." Sharc-Ft® is an implantable device designed for the arthroscopic or open surgery in the treatment of shoulder rotator cuff tears. The device is applied by following a transosseous approach, and "compasso" is used as a mobile shuttle to obtain lateral access of the tunnel throughout the humeral head. The main advantage of the above device with respect to other techniques is to prevent the bone cutting phenomena whilst ensuring a wide-based footprint reconstruction.

The latter technique uses a titanium device in a transosseous approach to be able to isolate the direct impingement between sutures and synthetic bone. In Fig. 2, the instrument used to create the tunnel is presented, including the device in the final configuration; in Fig. 3a, we reported an example of test block in which both approaches are shown before being tested.

Three configurations with the various block densities were considered in this study: traditional transosseous approach with 2 high resistance sutures (configuration 1), Sharc-Ft® with two sutures in the tip (configuration 2), and Sharc-Ft® with two sutures in the tip folded back in a closed ring (configuration 3). Fig. 3 shows a representation of the various test configurations.

For each combination of configuration and density value, displacement was measurement 5 times. Average value and standard deviation among the 5 repetitions were calculated for each combination.

A *t*-test with a confidence level of 95% was performed between configuration 1 and configuration 2 and between configuration 1 and configuration 3 (instead of the ANOVA analysis for a multiple comparison).

A failure analysis of the test block was conducted to analyze which areas are affected by superficial damage and, therefore, the source of gap formation.

#### 3. Results

Results from the *t*-test comparison between the three configurations are reported in Table 1 for each pcf value of the foam. The comparison shows significant differences between the configurations, in particular, between the traditional transosseous and the new approach with an interposed device.

The graphs of Fig. 4a correspond to the measured displacement in various test setups. In Fig. 4b, a direct comparison of the various configurations is reported. In general, for all the configurations, the higher the density pcf value, the larger the displacement (gap). More in particular,

Fig. 1. (a) Clamping system. (b) Pre-tension of the test sutures.

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Fig. 2. Sharc-Ft® system and related instrument to create the transosseous tunnel.

the graph related to configuration 3 reports lower displacement values with respect to the other two configurations, for all the density values. A significant improvement is for pcf values of 10 and 15 (Fig. 4a), which is even more relevant in configuration 3. Differently from configurations 1 and 2, configuration 3 shows a very similar displacement in the case of 30 and 40 pcf.

Regarding the traditional transosseous approach (configuration 1), we have to report that in a 10-pcf environment, not even the first loading cycle was completed (the whole bone bridge was destroyed in the first loading ramp, and no further loading capability was present in the repair).

By increasing the block density, the surface damage in the sutureblock contact decreased (in Fig. 5, pictures of the lateral entry hole are reported as an indication of a major gap source).

#### 4. Discussion

The transosseous approach has been known as a valid repair strategy. Over time, various criticisms were made about this technique mainly ascribable to two main categories: technical difficulties mainly related to the reproducibility in an all arthroscopic environment and stability of the construct (in the suture bone contact area).

la	bl	e	1	

Comparison between the various configurations and correspondent p value.

Configuration comparison	Average	SD	pcf	р
1 vs 2	10.02-4.96	0.04-0.18	10	< 0.001
1 vs 3	10.02-3.06	0.04-0.15	10	< 0.001
1 vs 2	5.51-4.10	0.24-0.13	15	< 0.001
1 vs 3	5.51-2.96	0.24-0.11	15	< 0.001
1 vs 2	3.66-3.32	0.25-0.19	20	0.007
1 vs 3	3.66-2.58	0.25-0.14	20	< 0.001
1 vs 2	3.40-2.72	0.16-0.13	30	< 0.001
1 vs 3	3.40-1.30	0.16-0.13	30	< 0.001
1 vs 2	2.34-2.34	0.11-0.11	40	1
1 vs 3	2.34-1.24	0.11-0.09	40	< 0.001

On the basis of the findings from Oguma, and further cited by Dines et al. (2010), the potential for type 2 collagen formation increases proportionally to the contact area and is therefore inversely proportional to the gap formation (defined as extension of the separation between tendon and bone contact).

The same concept was further developed by Ozbaydar (expanding the original work from St Pierre), remarking on the importance of keeping a steady contact in the initial regeneration phase (Özbaydar et al., 2008).

On the basis of the obtained results, we could conclude that the traditional transosseous approach by itself making use of high strength sutures leads to a significant increase in gap formation in a dynamic test configuration (for the effect of this impingement in the circled area, see Fig. 5).

By comparing the measured average displacement as a function of test block density, it is evident that there is a significant reduction of their values proportionally to the increase of block density.

The measured span range shifting from 10 to 40 pcf demonstrates a low reproducibility of the repair and how this is strongly affected by the bone consistency; we can therefore state that the construct stability (in terms of repair stiffness, ultimate load to failure and gap formation) is affected by bone quality, and to guarantee a successful result, it seems necessary to know the bone quality before taking the repair decision.

On the basis of our experimental experience, an effective way to mitigate this variability effect may be an increase of the number of sutures



Fig. 3. (a) Transosseous tunnel produced by "compasso" and Sharc-Ft® system in place on the left side; traditional transosseous approach on the right side. (b–d) Tested configuration: 1 (b), 2 (c), 3 (d).

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Fig. 4. (a) Displacement comparison in mm (gap formation) at the end of the test (average value based on 5 repetitions; the end of the test was determined when the first of the following 2 events occurred: failure of the bone bridge and load cycle no. 500). (b) Displacement comparison in the 3 different tested configurations.

that are passed in the tunnel in order to reduce the specific tension for each.

The suture–bone contact area seems to be the principal source of gap formation in a dynamic test configuration.

From our failure investigation conducted over the tested samples, we can clearly show the reshaped areas (areas where the original tunnel geometry was different); these are principally in the following spots: lateral entry hole and internal area (where the sutures come in contact with the bone).

The experimental evidence of this work is that by avoiding a direct impingement, we significantly reduce the gap formation during the test.

This conclusion was obtained also by Salata et al. (2012), who showed how performance improvement could be obtained by introducing one or more devices isolating the direct contact with the bone.

We have to keep in mind that although there is a certain correlation between ultimate load and gap formation, this is not always true, so specific in-depth analysis must be accomplished.

This trend, intended as gap formation, was also confirmed making use of an interposed device.

Of great importance, however, is the chosen suture configuration that can maximize, when the closed ring is recreated (as indicated in configuration 3), the stability of the construct through an optimal force balance and an overall reduction of gap formation (compared to what measured in configuration 2 in which the sutures are loaded only on the tip).

Therefore, by selecting test configuration 3, we are able to reproduce a construct that is by far more reproducible varying the test bone density. In fact, the performance is constant and the bone density should no longer be considered a variable affecting the quality of the repair in a transosseous approach.

Results obtained at high values of density deserve a special remark. Authors believe that when using configuration 3 at high values of density, displacement reveals a saturation effect. This is due to the fact that, going from configuration 1 to configuration 3, the elastic factor of the suture becomes prominent with respect to other factors. For example, in configuration 2, there can still be a small angle between the device and the brick while providing tension to the suture, resulting in a longer displacement. The same cannot happen in configuration 3, where the only factor influencing the displacement belongs to the elasticity of the suture.

The stability of the repair is more affected by the environmental conditions when sutures are loaded in the device only in the tip, without closing the ring. Despite this, performance is better anyway when compared to the classical transosseous approach. This is due to the slenderness and flexibility of the design.

With this work, it has been demonstrated how the traditional transosseous approach is strongly influenced by the bone quality up to the point where, in certain conditions, a safe and reliable repair could not be guaranteed.

Moreover, by monitoring the gap formation speed and progression in a traditional repair, the gap forms in the very early stage of the test (avoiding the repair stability even in the early phase when many authors agree upon the importance of keeping a steady contact), and it never stops but proceeds continually (the test cuff off was fixed, as indicated by many authors, at 500 cycles, but even the last cycles continue to increase the gap size).



Fig. 5. Direct impingement suture/sawbones with evident marks present at the end of the test (configuration 1). The red circles contain the superficial grooves induced by the impingement.

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In this study, synthetic material was used, being its physical properties in the order of the human cancellous bone. The purpose of the study was to examine what is the proper configuration that does not force the operator to know a priori the density value of the bone for each patient. An in vivo study involving real patients with different bone densities would be ideally the best method to evaluate in vivo results for a certain suture configuration. However, first, testing different suture configurations is not possible in the same bone area, and second, in vivo analysis on real patients would introduce many additional factors that can be directly related for example to the patient status and the level of lesion.

#### 5. Conclusions

What emerges from this study is the strict connection between performance and bone quality in a traditional transosseous approach and the related gap formation; the latter, as previously indicated, continues to increase over cycles and in certain density conditions cannot be considered a reliable way of fixing our tear.

Therefore, the desire of improving this result in a transosseous approach has been obtained by interposing a device isolating sutures from bone (Sharc-Ft<sup>®</sup>).

With this new approach, we avoid a direct impingement, and in the closed ring configuration (number 3), we mitigate the contact pressure and reduce the risk of local bone damage, also preventing the user to know a priori the value of bone density.

Further studies on real bones by means of cadaver specimens are required to continue the evaluation of the method in presence of muscles, under specific (passive) motions of the upper limb.

#### Sources of founding

None.

#### **Conflict of interest statement**

Author Matteo Mantovani report the following details of affiliation or involvement in an organization or entity with a financial or nonfinancial interest in the subject matter or materials discussed in this manuscript: paid employee for a company or supplier.

The rest of the authors disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work.

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### A 3D finite element model for geometrical and mechanical comparison of different supraspinatus repair techniques

Matteo Mantovani, PhD<sup>a</sup>, Andrea Pellegrini, MD<sup>b,\*</sup>, Pietro Garofalo, PhD<sup>a</sup>, Paolo Baudi, MD<sup>c</sup>

<sup>a</sup>NCS Lab Srl, Carpi, Italy

<sup>b</sup>Orthopedic and Traumatology Department, University of Parma, Parma, Italy <sup>c</sup>Orthopedic and Traumatology Department, University of Modena, Modena, Italy

**Background:** Contact pressure and contact area are among the most important mechanical factors studied to predict the effectiveness of a rotator cuff repair. The suture configurations can strongly affect these factors but are rarely correlated with each other. For example, there is a significant difference between the single-row technique and the transosseous or transosseous-like approaches in terms of footprint contact area coverage. A finite element model–based approach is presented and applied to account for various parameters (eg, suture pretension, geometry of the repair, effect of the sutures, geometry of the lesion) and to compare the efficacy of different repair techniques in covering the original footprint.

**Methods:** The model allows us to evaluate the effect of parameters such as suture configuration and position and suture pretension. The validity of such an approach was assessed in comparing 3 different repair techniques: single row, transosseous equivalent, and double row.

**Results:** Results from the application of the models show that the double-row and transosseous-equivalent techniques lead to progressive increase of the contact area compared with the single-row approach, supporting the conclusion that transosseous-equivalent fixation leads to an increase of the contact area and a better distribution of the pressure coverage.

**Conclusion:** The 3-dimensional finite element model approach allows multiple variables to be assessed singularly, weighing the specific influence. Moreover, the approach presented in this study could be a valid tool to predict and to reproduce different configurations, identifying how to reduce the stress over the tendon and when a repair could be effective or not.

Level of evidence: Basic Science Study, Computer Modeling.

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Keywords: Shoulder; cuff repair; finite element model; transosseous

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\*Reprint requests: Andrea Pellegrini, MD, University of Parma, Via Gramsci 14, I-43100 Parma, Italy.

E-mail address: a.pellegrini@aol.com (A. Pellegrini).

The arthroscopic approach in rotator cuff repair is a common surgical procedure. Even if rotator cuff repair studies are widely represented in the literature, the best method able to guarantee a superior functional outcome is still under discussion. Arthroscopic implants are subjected to continuous improvement, permitting complex constructs,

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doubling of the anchor rows, or a mixture between transosseous and anchor fixing. The challenge is to create a construct able to apply a higher compression in the footprint area and to maximize the contact extension.<sup>30,32</sup>

The biomechanical superiority of the double-row techniques is well supported in the literature.<sup>20,27</sup> The most frequently inspected factors are the ultimate load to failure in a static setup and the gap formation in a cyclic test.<sup>3,17</sup>

The importance of having a wider and more stable tissue-bone contact during the early phase of tissue regeneration is a key concept presented by many authors.<sup>10,22</sup> The common conclusion is that the methods that produce a smaller contact area and a smaller contact pressure have a potential risk for higher rates of structural failure.

It is important to distinguish between optimized pressure and not maximized because it is now evident that excessive pressure could be deleterious, producing vascular alteration, local stress spikes on the tendon side, and ischemic reaction, and so the optimal amount is that to prevent relative sliding at the bone-tissue interface.

Over the years, many investigations have been conducted of the various reparative approaches with the aim of finding the most effective one. Today, we can identify some key aspects on the basis of the successful rotator cuff repair: initial stiffness and strength of the repair (ultimate tensile strength), gap formation resistance, sliding stability in intra and extra rotation in the immediate postoperative period, maximization of the original footprint coverage, and optimization of the contact pressure at the tendon-bone interface.<sup>1,9,13,15</sup>

Previous works have presented attempts to reproduce the tendon-bone interface with the aim of identifying the most stressed area of the supraspinatus and finding a correlation with tears. Inoue et al<sup>14</sup> found the maximal tensile stress on the articular side of the anterior edge at 90° abduction.

The same results were also confirmed by Wakabayashi et al<sup>33</sup> in 2 findings: first, the articular side is a stress notch; and second, distal shift of stress concentration occurs with the arm in abduction.

Funakoshi et al<sup>12</sup> estimated the suture effect by dividing the experimental measured pressure by the projected suture area. They demonstrated that the stress concentration in a transosseous approach is 23.7% lower than in double-row techniques, without considering the effect of the weaker bone-suture interface. Whereas their findings were not obvious, their approach highlights the importance of the suture effect to the repair.

Another method can be found in Sano et al,<sup>27</sup> who applied a 2-dimensional model to assess the local stress peak due to the presence and position of the defect (lesion). Their study interestingly proved that it is possible to assess a partial intratendinous tear (delamination phenomenon) using a composite material.

Although for different purposes, Sano et al<sup>27</sup> assessed the local peak stress in the bone area close to the anchor

perties	used	in th	e finite	element	model

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Table I	Material properties used in the finite element model		
Tissue		Young modulus (MPa)	Poisson ratio
Supraspina	atus	168	0.497
Cancellous	s bone	13,800	0.300
Cortical b	one	13,800	0.300

insertion (as a function of anchor angle insertion). They focused on the importance of reducing the stress peak with the chosen repair approach not only in the soft tissue but also on the bone side.

The aim of this paper was to present a new approach for the comparison between various repairs in terms of footprint and contact area coverage. The new approach uses a finite element model-based method for evaluating the effect of parameters such as suture configuration and position and suture pretension. Second, the validity of such an approach was assessed in comparing 3 different repair techniques.

#### Materials and methods

Three-dimensional (3D) finite element models have been conceived to reproduce the various repair techniques: single row (SR), double row (DR), and transosseous equivalent (TE).

A commercial software, ANSYS R14 (ANSYS Inc, Canonsburg, PA, USA), was used as a preprocessor and postprocessor for the finite element analysis. The 3D model was obtained from a computed tomography scan. Computed tomography scans were performed on a cadaver specimen using 1-mm axial slices, a slice increment of <0.625 mm, and a field of view covering the entire humerus and scapula (as indicated by Levy et al<sup>16</sup>).

An anatomic coordinate system was created to measure the orientation in space of the humerus based on anatomic landmarks. The glenoid center point was determined by selecting the smooth surface of the glenoid face and calculating its center. A plane was fit to the selected glenoid face surface to create the glenoid face plane. A neutral inclination axis was defined between the glenoid center point and the trigonum spinae. Inclination was thus measured with respect to the neutral axis, and version was measured with respect to the scapular plane.

Cortical and cancellous bones have been treated as isotropic homogeneous and uniform materials (see Table I for the adopted material properties). The geometrical reproduction of the supraspinatus was based on what was measured in a cadaveric study by Pauly et al.<sup>26</sup>

In our analysis, we used 2 different solid elements, SOLID185 and SOLID285. The number of nodes on average is close to 45,000.

In this work, 3 different repair approaches have been simulated: SR, DR, and TE.<sup>24,25</sup> The abduction angle of the glenohumeral joint was fixed at the initial stage of validation of the model at  $0^{\circ}$  (position based on the coordinate system as described before). The models used to simulate the various repairs are described in Figure 1 (in all cases, the inserted devices have been



Figure 1 Solid models used in the finite element analysis. From *left* to *right*, single row (SR), double row (DR), and transosseous equivalent (TE).



Figure 2 Sketch of devices and suture positions used in the simulation. From *left* to *right*, single row (SR), double row (DR), and transosseous equivalent (TE).

considered not deformable and have been stabilized in the model with a bonded contact). The supraspinatus has been completely detached from the humeral head as is usually done in biomechanical studies, and contact with the humeral head is induced by the knot's pretension of the repair.<sup>12</sup>

The suture 3D models have been introduced in the cadaveric model, and the pretension effect has been simulated by connecting these to various springs having the same stiffness obtained from tensile tests on real sutures. The experimental data, in agreement with what has been reported in the literature,<sup>4</sup> was fixed at 5 N/mm.

The initial geometrical configuration (in terms of supraspinatus positioning) was the same for all the approaches. The geometry of the repair is sketched in Figure 2 for each type of repair.

A representation of the 3D mesh is shown in Figure 3; as visible from the mesh, there is a refinement that interests particularly the tendon and cortical bone in the contact area. Five elements in the thickness direction have been used to capture the gradient in the supraspinatus, and a properly sized mesh has been adopted at the interface with the sutures to capture the mutual pressure transfer.

Sutures were modeled as flexible cylinders having an external diameter of 0.4 mm and a modulus of ultrahigh-molecular-weight polyethylene, as described in Annex 1. The displacements of the distal part of the humerus were fixed in all directions at a distance of 150 mm from the tip of the tuberosity while a load of 200 N was applied uniformly in the tendon free surface. The load direction is tangential to the terminal part of the supraspinatus model.

By pretensioning the spring acting on the suture models at a 40 N load level, we introduce the knot-tying effect that leads to an



Figure 3 The 3D mesh used in the simulation.

interface pressure >0 between tendon and bone and between sutures and tendon.

The contact between the supraspinatus and bone has been treated as frictional, with a friction coefficient equal to 0.1; setting this option in ANSYS permits both parts to freely separate and slide and the contact to be modified by the suture effect, starting from the initial model at time 0 (with a preload level of 0 N). The load sequence is reported in the diagram of Figure 4.

To assess the contact area extension and the pressure distribution, we made use of an APDL (ANSYS Parametric Design



Language) macro script; a threshold pressure level of 0.0001 MPa was adopted when the contact area was computed. The maximum accepted interpenetration between bodies in the contact area is 0.001 mm. The surface considered by the macro and computed as the contact area consists only of the real tendon-bone interface, excluding the fixing device volume. At time 0 between tendon and bone, a geometrical gap of 0.05 mm was created. This gap was eliminated when the spring was pretensioned, simulating knot-tying action. Once the external load is applied, the initial contact area can change because of the lack of a counteracting downward pressure able to guarantee the stability of the initial contact.

The pretension forces, acting on the springs connected to the various sutures, were evaluated on the basis of the pressure measured by Tuoheti at al.<sup>30</sup> The different models have been evaluated from a geometrical standpoint, and we measured what we named the repair area, which is the area with a positive contact pressure greater than the threshold value.

#### Results

Table II reports the real active repair area, which excludes the presence of synthetic material (the typical anchor diameter widely used in in vivo and ex vivo study spans between 5 and 6 mm) over which the attachment is not possible.

Table II         Evaluated contact	areas of the va	rious techniques
Repair method	Repair area (mm²)	Contact area with a positive pressure (mm <sup>2</sup> )
Transosseous equivalent (4 anchors, 2 screwed and 2 impacted laterally)	103	42
Single row	35	15.9
Double row	87	26.8

The TE approach had a wider positive contact area. The SR technique produced by far the lowest footprint coverage compared with the other techniques. The DR technique provides an increase of the positive contact area equal to 69%, whereas the TE technique gives 164% more in comparison to the SR technique.

The area reported in the column "repair area" probably underestimates the real value, but the value reported in the last column represents the element area sum that displays a positive value of the contact pressure. By the macro described before, it is possible also to filter these data, excluding very low values (that cannot be considered of real effectiveness in a dynamic environment to prevent the tendon from sliding) and spurious peaks, which are more related to the model used instead of having a real physical meaning.

Figure 5 shows the representation of the contact area in the various constructs. What appears evident is the effect of the suture bridge configuration on the final computation of the contact area. It is evident how a different suture layout can significantly vary the final extension of the contact and the residual tension in the sutures, having a direct effect on the sliding resistance (Fig. 6).

#### Discussion

In this study, we presented a finite element method as an alternative to laboratory tests to compare various repair configurations. Even if the absolute values require a more extensive experimental validation (see Annex 1 for encouraging preliminary experimental results), we could consider this comparative approach a flexible tool that can be used to define the repair strategy supported by the biologic and mechanical factors that increase the probability of having an intact construct.

Previously reported findings<sup>12,14,27,28,33</sup> support finite element analysis as a promising tool to evaluate and to compare various repair configurations in an easy, fast, and flexible way. Indeed, mechanical factors are at the basis of a biologic healing process (mechanical stability, pressure distribution, contact area, reduction of local stress peaks).

In this study, biologic factors were not considered. The problem was addressed from a mechanical standpoint, and

#### Supraspinatus repair techniques with 3D finite element models



**Figure 5** Qualitative maps of the supraspinatus-bone contact layout; *orange* represents the area in contact with a positive applied pressure. The free surfaces are in *yellow*, and the absence of any contact (device insertion areas) is shown in *blue*. *Upper left*, single row (SR); *upper right*, double row (DR); *lower left*, transosseous equivalent (TE).



**Figure 6** Direct comparison of how a "dead area" (*left side*, evidenced by the *red circle*) is transformed in a compressive area through the use of a bridging configuration (*right side*, evidenced by the *red circle*).

the configurations that maximize some geometrical and mechanical factors considered the basis of the healing process were discovered. These factors could be identified as area of contact, pressure and pressure distribution over the contact, avoidance of local peak stress, and reduction of the tension over the repair. Milano et al<sup>19</sup> have interestingly demonstrated how excess tension applied over the repair can significantly impair the biomechanical results. The biologic relation between applied pressure at the soft tissue–bone interface and the integrity of the repair has been demonstrated.<sup>11</sup>

Several studies evaluated repair integrity, which we consider of importance,<sup>11,19,29</sup> such as Duquin et al,<sup>11</sup> who compared mechanical stability and repair integrity.

Many papers have compared SR and DR techniques in terms of clinical outcomes, also looking at biomechanical and anatomic constructs.<sup>5,7,10,11,31</sup> Data collected in our study suggest how the SR approach gives several high-stress peaks in the areas close to the anchor's position; these pressures decrease sharply in the interanchor space.

Our study follows previously reported trends,<sup>2,6,18-21,23,24</sup> and highlights important aspects of repair techniques. Suture bridging between the various anchors or tunnels (in the case of a transosseous approach) appears to be essential to increase contact area. Suture bridges are effective not only for their load sharing effect that reduces local peaks, but also to make a "dead area" (defined as the footprint area between anchors that in some repair configurations presents a zero contact pressure) active in the repair zone.

Another interesting finding is the effect of humeral head shape on contact asymmetry, as it is evident that footprint shape strongly influences contact pressure. Reshaping by decortication will significantly increase compression in transosseous techniques, and maintain tight contact between soft tissue and bone. A stable construct can enlarge the contact pressure and normalize pressure distribution, which may help keep the repair intact. Our proposed method may maximize footprint area coverage to enhance repair integrity.

Following the guidelines provided by Viceconti et al,<sup>32</sup> we are aware of the approximations introduced in this model. However, the purpose of our study was to compare the efficacy of different repair techniques, and we do not feel the simplifications biased our conclusions.

There are limitations to this study which would require validating the results in an experimental setup; however, comparing similar results in the literature, ours follow the data trends, but the results are extremely dispersed.<sup>2,6,18,20,25</sup>

Our approach allows assessment of multiple variables, and seems promising. Dar<sup>8</sup> reported that statistical methods should also be implemented for a more comprehensive comparison of various techniques.

#### Conclusion

Our study confirms that DR and TE repairs lead to an increase of the contact area and to a better distribution of the pressure coverage. Although the finite element method is a theoretic one, the approach we presented could be a valid tool to predict and reproduce different configurations and to infer conclusions concerning different repair approaches. Further biomechanical studies are required to compare the repair techniques in this study.

#### Disclaimer

Pietro Garofalo is employed as Product Manager at NCS Lab Srl (Carpi, Modena, Italy).

Matteo Mantovani is Technical Director at NCS Lab Srl (Carpi, Modena, Italy).

The other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

#### Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jse.2015.09.002.

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## **CLINICA ORTOPEDICA** UNIVERSITA' DEGLI STUDI DI PARMA

## REHABILITATION WITH A TRANSOSSEOUS APPROACH: COMMON WAY OR DIFFERENT PROTOCOL?





There's none so blind as they that won't see.

(Jonathan Swift)



Andrea Pellegrini, MD

I have no potential conflicts with this presentation. WHAT'S THE PURPOSE OF RCR SURGERY? RESTORATION OF:

- Pain free
- Fully functional
- Powerful motion



### Post-operative rehabilitation after surgical repair of the rotator cuff

Table 2 Objectives of the various rehabilitation stages		
Stage	Objectives	
1	Prevention of joint stiffness due to post- operative adherences	
2	Progressive recovery of the range of passive movement without scapular compensation	
3	Recovery of strength and of physiological scapulohumeral rhythm	
4	Complete the recovery of the power and normal actions for both work and sports	

1: 4-6 weeks sling only PROM
2: until 12 weeks stretching with terapist
3: begins around the third month with muscular toning stage with progressive functional recovery
4: 4-6 months is different depending on the type of patient (work, sports) Marco Conti · Raffaele Garofalo · Giacomo Delle Rose · Giuseppe Massazza · Enzo Vinci · Mario Randelli · Alessandro Castagna

#### Musculoskelet Surg (2009) 93:S55–S63 DOI 10.1007/s12306-009-0003-9

#### Table 1 Stages of the tendon healing process

Stage (duration)	Evolution of the process
Inflammatory (0–14th day)	Leucocytes, lymphocytes, monocytes Release of histamine and bradykinin which increase vascular permeability Increase of platelets <i>in situ</i> Initial scar thanks to fibrin and fibronectin
Proliferative (2nd-3rd/4th week)	Inflammatory tissue replaced by fibroblasts, myofibroblasts and endothelial cells Formation of granulation tissue Tighter tendon-bone adhesion Production of collagen III (immature) by fibroblasts (after 15 post-op days)
Maturation and remodelling (3rd–4th week – 12th/26th week)	Maturation of the scar tissue Collagen III replaced by mature collagen I Formation of dense connective tissue Integration of the tendon in the bone

#### **CONSENSUS STATEMENT**

CrossMark

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SHOULDER AND

SURGERY

### The American Society of Shoulder and Elbow Therapists' consensus statement on rehabilitation following arthroscopic rotator cuff repair

Charles A. Thigpen, PT, PhD, ATC<sup>a,b,\*</sup>, Michael A. Shaffer, MSPT, OCS, ATC<sup>c</sup>, Bryce W. Gaunt, PT, SCS<sup>d</sup>, Brian G. Leggin, PT, MS, OCS<sup>e</sup>, Gerald R. Williams, MD<sup>f</sup>, Reg B. Wilcox III, PT, DPT, MS, OCS<sup>g</sup>

we favor:

passive, limited ROM starting within the first 6 weeks postoperatively. Once passive mobility is established and the repair begins to sufficiently heal, active motions can begin. Rehabilitation loads on the RCR progress from concentric motions with short levers and gravity-minimized positions to longer levers performed against the resistance of gravity. When the repair is sufficiently strong (approximately 12-16 weeks),

## **Phase I: Protection**





## **Phase II: restoration of functional ROM**



## **Phase III: early strengthening**









Timeline for Healing and Strength of Repair

?

Too scared???



## WHAT DO WE KNOW ABOUT TENDON HEALING ?



Tendon to Bone Healing: Differences in Biomechanical, Structural, and Compositional Properties Due to a Range of Activity Levels

# 8 week timepoint



Collagen orientation in the CTL A, IM B, and EX C groups at the 8 week timepoint. Note the decreasing level of organization when comparing CTL most organized, A,IM B, and EX least organized, C Chronic Rotator Cuff tears are at risk for early Motion after repair due to tendon stiffness... Ward SR et al.: Plasticity of muscle architecture after supraspinatus tears. J Orthop Sports Phys Therap. 2010

The Tendon-bone attachment remains immature (weak) For the first 12 weeks after surgery. Sonnabend DH et al: JBJS 2010

Passive ROM after repair does not effect tendon Mechanical properties after repair. Peltz CD et al: JBJS 2009

Reformation of normal tendon-bone connection after Repair takes 24 weeks. Koike Y et al: J Orthop Res 2005

Rotator cuff strength recovery takes 6 weeks after Tendon repair. Trudel G, et al: J Orthop Res 2010

Cortisone injections interfere with tendon healing. Mikolyzk DK et al: JBJS 2009

Smoking interferes with tendon healing. Galatz LM et al: JBJS 2006



# The value of cryotherapy



### The efficacy of continuous cryotherapy on the postoperative shoulder: A prospective, randomized investigation

Hardayal Singh, MD,<sup>a</sup> Daryl C. Osbahr, BS,<sup>b</sup> Thomas F. Holovacs, MD,<sup>a</sup> Patrick W. Cawley, DSc, OPA, RT,<sup>c</sup> and Kevin P. Speer, MD,<sup>d</sup> Durham and Cary, NC, and Vista, Calif



WYSIO RECLIP

The Effect of Continuous Cryotherapy on Glenohumeral Joint and Subacromial Space Temperatures in the Postoperative Shoulder

Daryl C. Osbahr, B.S., Patrick W. Cawley, D.Sc., O.P.A., R.T., and Kevin P. Speer, M.D.

## Non pharmacological method for pain control
# Does a brace influence clinical outcomes after arthroscopic rotator cuff repair?

M. Conti<sup>1</sup> · R. Garofalo<sup>1,2</sup> · A. Castagna<sup>1</sup>



Patients operated with isolated superior or posterosuperior rotator cuff tear immobilised with brace in 15 of ER position showed less pain and a better passive range of motion at short time after surgery.

- pillow at average 30 in the scapularplane has been reported to reduce the tensile force on the repaired superior cuff (Hatakeyama Y, 2001)
- arm adducted at side could result in a hypovascularity of the supraspinatus (Rathbun JB, 1970)

Can suture fixation help the healing?? Different divices for arthroscopic repair in the hands of surgeons:

- anchors
- pushlock, versolock
- transosseous suture

# - SHARC-FT

## **Differences in these divices??**

- Biomechanics
- Tendon-bone contact
- Tendon pressure distribution
- Devices migration or pull-out



A 3D finite element model for geometrical and mechanical comparison of different supraspinatus repair techniques

Matteo Mantovani, PhD<sup>a</sup>, Andrea Pellegrini, MD<sup>b</sup>,\*, Pietro Garofalo, PhD<sup>a</sup>, Paolo Baudi, MD<sup>c</sup>

> SHOULDER AND Elbow Surgery



Gap formation in a transosseous rotator cuff repair as a function of bone quality



M. Mantovani<sup>a</sup>, P. Baudi<sup>b</sup>, P. Paladini<sup>c</sup>, A. Pellegrini<sup>d,\*</sup>, M.A. Verdano<sup>d</sup>, G. Porcellini<sup>c</sup>, F. Catani<sup>b</sup>

## Will stifness be a problem if no early motion?

Postoperative Stiffness is rare after arthroscopic rotator cuff repair. Denard P et al: Arthroscopy 2011

Patients with higher risk for stiffness: PASTA repair, calcific tendonitis, those Already stiff, concomitant labral repair. Individualized program with early motion May be indicated for these.

Koo SS et al: Arthroscopy 2011

Delayed motion in large RCR does not lead to stiffness, Healing rate may be higher in these patients c/w early Motion patients.

Parsons BO, et al: JSES 2010

Pendulum exercises immediately after surgery may load The repair and pose risk.

Long JL et al: J Orthop Sports Phys Ther 2010

	Postoperative weeks 1-6	Postoperative weeks 6-12	Postoperative weeks 8-16	Postoperative weeks 12-20	Postoperative week 20 and late
Initiation phase	Phase 1	Phase 2	Phase 2-3	Phase 3-4	Phase 4
EMG activity level	≤15%	≤15%	16%-29%	30%-49%	≥50%
Exercise goal	PROM	AAROM or AROM	AROM or resisted	Endurance	Strengthening
Exercises*	Pendulum <sup>30,69,74</sup>	Towel slide or horizontal dusting <sup>36,113</sup>	Pulley FE <sup>30,36,74</sup> Incline dusting <sup>115</sup>	High, middle, and low scapular rows <sup>47,84</sup>	Upright FE 3-4 lb, 10-rep max <sup>93,94,108</sup>
	Forward bow <sup>113</sup>	AAROM supine washcloth press-up <sup>113</sup>	Ball roll on wall <sup>36</sup> Upright wall slide <sup>36,74,115</sup>	Standing dumbbell ER at 0° abd, 10-rep max <sup>93</sup>	Side-lying dumbbell ER at 0°, 10-rep max <sup>93</sup>
	Therapist-assisted FE <sup>30,74</sup>	AROM supine press-up <sup>113</sup>	FE with upright T-bar AAROM elevation <sup>36,74</sup>	Standing dumbbell ER in scapular plane, 10-rep max <sup>93</sup>	Prone horizontal abd, 10-rep max <sup>93,94</sup>
	CPM in FE <sup>30</sup>	Side-lying supported active elevation <sup>36</sup>	Upright T-bar AAROM FE, active lowering <sup>36</sup>	Elastic resistance shoulder flexion <sup>84</sup>	Prone ER at 90° abd, 10-rep max <sup>93</sup>
	Self-assisted supine FE <sup>30,74,113</sup>	AROM reclined wedge press-up <sup>113</sup>	Upright active FE with no weight <sup>36,113</sup>	Elastic resistance throwing accelerate <sup>84</sup>	Seated military press <sup>11</sup>
	ER/IR self-assisted	Supine elastic band FE <sup>36</sup>	Upright active FE 1 lb <sup>113</sup>	Elastic IR at 90°84	Elastic resistance ER at 90°84
	with stick <sup>30,74</sup>	Aquatic FE slow speed <sup>55</sup>	Aquatic FE fast speed <sup>55</sup> Side-lying dumbbell ER at 0°, resistance of 25% MVIC <sup>3</sup>		Elastic resistance throwing decelerate <sup>84</sup>
			Prone dumbbell ER at 0°, resistance of 25% MVIC <sup>3</sup> Elastic resistance ER IR and for	ward pupch <sup>21,47,84</sup>	Standing dumbbell ER at 90° abd, 10-rep max <sup>93</sup>

AAROM, active-assistive range of motion; abd, abduction; AROM, active range of motion; CPM, continuous passive motion; EMG, electromyographic; ER, external rotation; FE, forward elevation; IR, internal rotation; max, maximum; MVIC, maximum voluntary contraction; PROM, passive range of motion; rep, repetition.

\* Exercises were grouped based on published supraspinatus EMG activity.

<sup>†</sup> Mean EMG activity levels for these exercises span from <15% to >50%, with the study by Hintermeister et al<sup>40</sup> being the only study showing mean values <15%. However, the maximum EMG activity level in their study ranged from 25%-48%; thus, these exercises are best categorized in the 16% through ≥50% categories depending on the resistance level.





### Is Early Passive Motion Exercise Necessary After Arthroscopic Rotator Cuff Repair?

Yang-Soo Kim,\* MD, PhD, Seok Won Chung,<sup>†</sup> MD, Joon Yub Kim,<sup>†</sup> MD, Ji-Hoon Ok,\* MD, In Park,\* MD, and Joo Han Oh,<sup>†‡</sup> MD, PhD Investigation performed at the Department of Orthopaedic Surgery, Seoul National University College of Medicine, Seoul National University Bundang Hospital, Korea

The American Journal of Sports Medicine

# LEVEL I STUDY

# **Early passive ROM exercise is not necessary after RCR**

### Prospective randomized study of arthroscopic rotator cuff repair using an early versus delayed postoperative physical therapy protocol

Derek J. Cuff, MD\*, Derek R. Pupello, MBA

### LEVEL I STUDY

no significant advantage (CMS, Dash)cto beginning early passive range of motion after surgery. Patients in the delayed range of motion group had a slightly higher rotator cuff healing rate by ultrasound imaging, indicating that there may be a potential benefit to avoiding early passive range of motion in an effort to protect the surgical repair.

# The Constant score and the assessment of scapula dyskinesis: Proposal and assessment of an integrated outcome measure

Andrea Giovanni Cutti<sup>a,\*</sup>, Ilaria Parel<sup>b,c</sup>, Andrea Pellegrini<sup>c,d</sup>, Paolo Paladini<sup>c</sup>, Rinaldo Sacchetti<sup>a</sup>, Giuseppe Porcellini<sup>c</sup>, Giovanni Merolla<sup>c</sup>



Time	CMS (absolute and %)	SW-CMS (absolute and %)	(CMS – SW-CMS)/CMS (%)
45	0 (0%)	0 (0%)	0
70	4 (19%)	2 (9.5%)	50
90	10 (31%)	3 (9.5%)	70
FU	28 (87.5%)	16 (50%)	43

### Early Versus Delayed Passive Range of Motion After Rotator Cuff Repair

### A Systematic Review and Meta-analysis

Melissa A. Kluczynski,\* MS, Samir Nayyar,\* MD, John M. Marzo,\* MD, and Leslie J. Bisson,\*<sup>†</sup> MD Investigation performed at the University at Buffalo, The State University of New York, Buffalo, New York, USA

The American Journal of Sports Medicine

# SA vs TO vs DR vs SB Repaired rotator cuff should consider initiating

PROM immediately after RC repair to reduce retear rates for small tears but should consider delaying PROM for repair of large tears

SA repair of large tears has a very high failure rate

### Does Early Versus Delayed Active Range of Motion Affect Rotator Cuff Healing After Surgical Repair?

### **A Systematic Review and Meta-analysis**

Melissa A. Kluczynski,<sup>\*</sup> MS, Maureen M. Isenburg,<sup>\*</sup> BS, John M. Marzo,<sup>\*</sup> MD, and Leslie J. Bisson,<sup>\*†</sup> MD *Investigation performed at the University at Buffalo, The State University of New York, Buffalo, New York, USA* 

The American Journal of Sports Medicine

# SA vs TO vs DR vs SB

early active ROM may be harmful to the healing process for small and large tears regardless of repair method. Delaying active ROM by at least 6 weeks after RC repair may be advisable for healing the tissue

# Our experience...

Ultrasound and clinical evaluation of massive rotator cuff tear repair using transosseous sharc-ft technique at 6 months of follow up: a preliminary study.



Figure 2. <u>Ultrasound at 6 months</u> follow-up <u>demonstrates</u> regular <u>insertion (arrow)</u> of the <u>supraspinatus tendon</u> (SS) over <u>humeral</u> head (HH) and suture (head <u>arrow</u>).



Figure 1. X-ray in true AP projection in extra-rotation (a) and axillary projection (b) showing clearly no mobilization of sharc-ft device.

**15 patients** 

- Less than 3 cm
- 2 weeks of sling
- **PROM 2-6** w
- AROM after full PROM
- 6 months of f/u
- No re-tear

- No data about SHR and post-op
- No evidence early motion is better than delayed
- No evidence if suture technique can help the choice
- No study on rehab about the new transosseous approach
- PROTECTION OF THE
   TENDON HEALING IS
   MANDATORY



## **CLINICA ORTOPEDICA** universita' degli studi di parma

# THANK YOU FOR YOUR ATTENTION



Thanks to the Shoulder Journal Club for the help!!

# CLINICAL EVALUATION OF TRADITIONAL TRANSOSSEOUS AND FISH-FIT MD ROTATOR CUFF REPAIR





**Rasia Dani E.<sup>1</sup>, Giulini G. M.<sup>1</sup>, Mantovani M.<sup>2</sup>** <sup>1</sup>ULSS 20, Ospedale "Girolamo Fracastoro" – Via Circonvallazione 1, 37047 San Bonifacio (VR) – ortopedia@ulss20.verona.it <sup>2</sup>NCS Lab Srl - Via Pola Esterna 4/12, 41012 Carpi (MO) – matteomantovani@ncs-lab.com

### Introduction

The goal of rotator cuff repair is to achieve high initial fixation strength, minimize gap formation restoring a wide foot-print, maintain mechanical stability under cyclic loading and optimize the biology of tendon-bone healing.

Several works<sup>1,2</sup> have shown how rotator cuff tears repaired by a transosseous approach are able to obtain a better functional reconstruction and a relevant pain reduction compared to others repairing ways. For many years, however, this technique was restricted only to open or mini-open surgery because of its difficulty. Nowadays, thanks to the quickly technological evolution occurred in the last years in this field, it is possible to perform a transosseous repair also in arthroscopic surgery, joining the effectiveness of the technique in the recovering of the shoulder functionality and in the pain reduction with the rate and the safety of the surgical procedure.

### A mid-step: transosseous equivalent, is it?

The first step to approach the arthroscopic transosseous technique in rotator cuff repair was the called, transosseous equivalent technique. This approach, that involves the construction of a medial row in the foot-print region, and a lateral row on the great tuberosity rim, attempts to replace the transosseous technique, making the arthroscopic procedure easier, but without achieving the same biomechanical behavior for two main reasons:

- interface between suture and tendon is critical because force isn't dissipate along all suture loop,
- possibility of device migration due to weak bone quality.



Figure 1: Rx image of an implanted Fish-Fit MD device.

ADVANTAGES	DISADVANTAGES
<ul> <li>Excellent outcome data<sup>3</sup></li> </ul>	<ul> <li>Difficult to perform</li> </ul>
<ul> <li>Low cost</li> </ul>	<ul> <li>Time to perform</li> </ul>
<ul> <li>Wide foot-print<sup>4</sup></li> </ul>	<ul> <li>Suture-bone cut effect</li> </ul>
<ul> <li>Good contact pressure<sup>4</sup></li> </ul>	
<ul> <li>No device migration<sup>5</sup></li> </ul>	

### The solution: Fish-Fit MD

Fish-Fit MD is a suture platform for the treatment of rotator cuff tears developed to overcome the traditional transosseous approach deficiencies in arthroscopy. The device has a slotted body designed to manage one to four inner sutures (more are also possible), his shape was created to maximize the resistance to pull-out effect and to prevent suture-bone interaction. The head provides high stability to the system due to the external sutures that achieve a force equilibrium.

One of the main device features refers to his placement in a region with a good bone quality, located about 15/20mm distally to the great tuberosity rim. This capability allows to obtain a significant decrease in the possibility of repairing failure due to suture bone cut effect. Furthermore the device behaves as a bridge, improving the way suture impact over bone. To overcome the traditional difficulties related to the transosseous arthroscopic repair procedure, the device and the required sutures can be placed through specific surgical instrumentations that allow to perform a guided and repeatable procedure saving operative time.





Figure 2: Arthroscopic view of rotator cuff repair performed with Fish-Fit MD . Classic transosseous Vs. Fish-it MD: clinical outcome

Thirty patients were found suitable to be treated with Fish-Fit MD device. All 30 patients were available for follow-up at a mean of 6,4 months (range, 3 to 12 months). There were 16 men and 14 women, with a mean age of 63,6 years (range, 41 to 77 years). All patients had suturable massive tears (wider than 3 cm) that affected one or more tendons. The repair configuration involved the use of 1 or 2 (one patient) devices with only transosseous sutures for the medial row and external sutures for the lateral

Figure 3: Fish-Fit MD Constant-Murley score normal distribution before surgery and at 3 and 6 months (top-left); Comparison of Constant-Murley score distribution between Fish-Fit MD and Classic transosseous (top-right); Statistical data of Fish-Fit MD clinical outcomes (bottom-left); Comparison of Constant-Murley score normal distribution between Fish-Fit MD and Classic transosseous (bottom-right).

### row. After surgery the upper limb was immobilized for 20 days, allowing only shoulder and elbow passive mobilization. The patient were reviewed after 3, 6 and 12 months for assessment and evaluation throw Constant-Murley Shoulder Outcome Score, RX and RMN imaging.

The patients shown a mean Constant-Murley Score of 23,2 (range, 12 to 71) pre-surgery. After 3 months the mean score was 63,0 (range, 43 to 82), the strength tests were performed with 2 kg weights and corresponding reduced score. After 6 months the mean score achieved from patients was 83,1 (range, 41 to 89). Finally, after 12 months, the mean score related to 10 patients was 86,9 (range, 73 to 89).

The study compared this data with results obtained from thirtytwo patients with massive rotator cuff tears treated with a classic transosseous approach. All patients were available for a 6 months follow-up. There were 17 men and 15 women, with a mean age of 61,2 years (range, 36 to 75 years).

### CONCLUSIONS

The compared study between rotator cuff tears repaired with Fish-Fit MD device and through a classic transosseous approach, shows at 6 months a clinical outcome data (Figure 3) that indicates a statistically significant results improvement in patients treated Fish-Fit MD device (P<0,005), furthermore no RX imaging revealed device migration in all patients treated with it.

### Fish-Fit MD: flexible in repair

Among Fish-Fit MD features, one of the most distinctive, is the opportunity to perform a wide and personalized range of repairs. This capability is due to his structure, that allows to use it as a suture platform with a variable number of internal and external sutures which can be arranged in many configurations. As mentioned, the device can manage up to four internal sutures and two external, which can be organized according to tendon tears and to preferences in the surgical procedure (Figure 4).

To perform a more freely repair, when massive tears were found, surgical instrumentations allow to realize multiple medial holes, 2-3mm in diameter, through a single 3mm lateral hole, allowing to obtain a more suitable sutures distribution. Seldom, when a rotator cuff reconstruction is needed, it is also possible to use two implanted devices, in such a way to manage a higher number of sutures.



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- 5. Benson E. C., MacDermid J. C., Drosdowech D. S., Athwal G. S.; The Incidence of Early Metallic Suture Anchor Pullout After Arthroscopic Rotator Cuff Repair; Arthroscopy; Arthroscopy, Vol 26, No 3, 2010: pp 310-315

Figure 4: RCR through Fish-Fit MD with two internal sutures for tendon to bone compression and two external sutures for pulling the tendon (first); : RCR with Fish-Fit MD and three internal sutures that close the suture loops passing through the eyelet on the device (second); RCR with Fish-Fit MD where the three internal sutures were fixed with a knot to the device head (third); RCR of a massive tear with Fish-Fit MD and four internal sutures (fourth).



TRANSOSSEOUS RCR ACADEMY FEBRUARY 7<sup>th</sup>, 2017

### Advantages Of Arthroscopic Transosseous Rotator Cuff Repair

### A Prospective Randomized Clinical Trial

### Pietro Randelli



UNIVERSITÀ DEGLI STUDI DI MILANO Dipartimento di Scienze Biomediche per la Salute Università degli Studi di Milano Direttore I^ Divisione Istituto Ortopedico G. Pini



# Rotator Cuff Tears

> Rotator cuff lesions are the most common cause of shoulder disability

Prevalence in cadaveric studies ranges from 5 and 40% of the population (with a significantly increase over the age of 60)

Teunis T, Lubberts B, Reilly BT, Ring D. A systematic review and pooled analysis of the prevalence of rotator cuff disease with increasing age. *J Shoulder Elb Surg*. 2014;23(12):1913-1921. doi:10.1016/j.jse.2014.08.001.

Tashjian RZ. Epidemiology, natural history, and indications for treatment of rotator cuff tears. *Clin Sports Med.* 2012;31(4):589-604. doi:10.1016/j.csm.2012.07.001

Despite the high prevalence of the disease, there is not a consensus about the choice of treatment









Knee Surg Sports Traumatol Arthrosc. 2015 Feb;23(2):344-62. History of rotator cuff surgery. Randelli P, Cucchi D, Ragone V, de Girolamo L, Cabitza P, Randelli M.



#### Surgical Techniques

#### ArthroTunneler Surgical Technique







Step 1

Drill medial tunnel(s) to a positive stop using the Drill Guide and 2.9 mm Drill - M. Drill additional tunnel(s) at this time depending on the size of tear and type of final repair construct desired.

#### Step 2

Insert tip of the Hook into the medial tunnel until the top bar of the Hook is flush and parallel with the footprint.



#### Step 3

Deploy the nitinol Loop into the medial tunnel. Insert the 2.5 mm Drill - L through the device and drill through the Loop to a positive stop.



### Step 4

Remove the 2.5 mm Drill -L, then replace it with a loaded Suture Inserter.



#### Step 5 Remove the Suture Inserter, then retrieve the nitinol Loop remove the ArthroTunneler to capture the suture loop.



#### Step 6

Retract the Anvil and with the attached suture loop from the repair site.



#### Step 7

Remove the suture loop from the ArthroTunneler by deploying the nitinol Loop and pulling the device away from the suture.



Step 8

Pass the suture loop through the cuff and use it as a definitive repair suture, or, use the suture loop as a shuttle to pass multiple sutures through the intersecting bone tunnels.



#### Step 9

Repeat steps #2 through #8 for each additional tunnel. Pass sutures through tendon(s) using desired technique that is applicable to the patient's anatomy. Tie and cut sutures to complete the repair.









X-BOX configuration



# • Our study

### Objective

• Comparison of clinical and radiological outcome of arthroscopic rotator cuff repair with metal anchors vs transosseous tunnel technique

### > Hypothesis

- Substantial uniformity of results between the two techniques
- Post-operative pain reduction in transosseous repair technique



## Arthroscopic rotator cuff repair: two different techniques

Anchors







**Transosseous tunnel** 





### Spontaneous, prospective, randomized, controlled, double-blind clinical trial.

The protocol study was

- approved by the Hospital Ethical Committee (authorization number 2769; January 29, 2013);
- registered at ClinicalTrials.gov (ClinicalTrials.gov ID: NCT01815177; March 3, 2013).

The sample was calculated with a reduction of Pain Score of 2 points, with a standard deviation of 2 points, power of 80% and alpha value of 5%, the <u>minimum number of patients to be enrolled per group was 17</u>, allowing for a possible drop-out of 10-15% of the patients.







• Flow diagram of the study

# Patient evaluation

### Assesment tool

### Clinical scores

- Constant Analysis
- QuickDASH Analysis
- NRS Scale
- Radiological assessment
  - MRI





# Study Protocol

### **<u>Pre-operative evaluations</u>**:

• MRI, NRS, Costant score, QuickDash score

### **Post-operative evaluations:**

### 1-28 days after surgery:

• NRS

### **2-Month FU:**

• Passive ROM evaluation (Flex, Er, Ir), NRS

Chung SW, Kim JY, Kim MH, Kim SH, Oh JH. Arthroscopic Repair of Massive Rotator Cuff Tears: Outcome and Analysis of Factors Associated With Healing Failure or Poor Postoperative Function. Am J Sports Med. 2013;41(7):1674-1683.

### > **1-Year FU:**

• MRI, NRS, Costant score, QuickDash score





### • 15 months mean FU

	Mean	SD
Age	54,5	6,8
Lesion Dimension (mm)		
AP	20,6	10,3
ML	20,2	13,9
Anchor n°	1,3	0,4
Tunnel n°	1,6	0,6
Suture per Anchor n°	3,2	1,3
Suture per Tunnel n°	4,0	1,4





# Post-operative Pain



Weekly post-operative pain NRS score



- No significant difference in daily pain reduction
- <u>Faster pain reduction with transosseous</u> <u>technique</u>
- Significantly lower NRS weekly mean score in the III° and IV° post-operative week with transosseous technique
- Hardwareless technique may favour postoperative pain reduction



# Post-operative functionality score improvement (> 1-year FU)





■ Pre-op Mean ■ Post-op Mean



\*\* p-value < 0,01, \*\*\* p-value < 0,001



# Post-operative score comparison

### **Post-operative score comparison**





# Sugaya Classification

- Rotator cuff with sufficient thickness in comparison to normal rotator cuff and with homogeneous <u>hypointensity</u> signal (type I)

- Rotator cuff with sufficient thickness in comparison to normal rotator cuff associated with partial areas of hyperintensity (type II)

- Insufficient thickness of rotator cuff, reduced to less than 50% compared to a healthy shoulder but without discontinuity. This framework suggests lesions with partial <u>delamination</u> (Type III)

- Presence of minor discontinuities in 1 or 2 images, indicative of small full-thickness lesion (type IV)

- Presence of major discontinuities observable in more than 2 images, suggestive of medium or large full-thickness lesion (Type V)







- Overall re-rupture rate of 13% (11% minor discontinuity and only 2% full-thickness lesion).
- Difference in frequency of negative cases not significant between the two techniques (p=0,81).
- No Tunnel Break-down were observed



# Final follow-up

- 40 months (range 31-46)
- Quick dash
- No differences



# Conclusions

- Results obtained (42 month mean FU) demonstrate that the transosseous repair is as good as anchors repair.
- Pain reduction is quicker in the Transosseous group, probably due to the fact that the technique is hardware free.

Paper accepted for publication in the American Journal Sports Medicine
 DOI 10.1177/0363546517695789



### GRAZIE





pietro.randelli@unimi.it



# What is the Scientific Rational in Transosseous Approach?



### Cory Edgar M.D., Ph D. Assistant Professor Department of Orthopedic Surgery UConn Health Center Team Physician:

UConn Athletics

Connecticut College

US Coast Guard Academy







## Pleasure to be here ----



HUSKIES

# Disclosures



**Research Support/Collaboration :** 

We have a Research Grant Collaboration that supports a research regarding this product





## **Research Team**





MEDICAL DEVICES FACTORY


#### What are Current Issues with Rotator Cuff Outcomes?

1. Optimizing the Healing at the Tendon to Bone interface: Enthesis



The Enthesis: a review of the tendon-to-bone insertion. **Apostolakos** and Mazzocca. Muscles, Ligaments and Tendons Journal 2014; 4 (3): 333-342

Figure 3. Illustration of the four zones of the enthesis superimposed on a histological section of a mouse supraspinatus. Proteoglycans in tendon, fibrocartilage and calcified fibrocartilage are seen in purple after staining with toluidine blue, which highlights the compositional gradient characteristic of the enthesis.

	Composition	Significance
Zone 1 Pure Dense Fibrous Connective Tissue	Fibroblasts Type I Collagen Type III Collagen (1,8,10,11)	Linearly arranged collagen with mechanical properties similar to mid-substance tendon (1,8,10,11)
Zone 2 Uncalcified Fibrocartilage	Fibrochondrocytes Proteoglycan aggrecan with Collagen (Types I-III) (1,2,8,10-14)	Dissipates bending of collagen fibers in tendon (2)
Tidemark		Basophilic demarcation between uncalcified and calcified fibrocartilage representing the boundary between soft and hard tissues (8)
Zone 3 Calcified Fibrocartilage	Fibrochondrocytes Type II Collagen (Predominant) Type I Collagen Type X Collagen (1,2,3,10-14)	Irregularity of attachments into bone give mechanical integrity of enthesis (2)
Zone 4 Bone	Osteocytes Osteoblasts Osteoclasts (1,8) Type I Collagen	Provides sites of attachment for the tendon



### What are Current Issues with Rotator Cuff Outcomes?

- 2. Fixation Strength of the Construct: Bridging the gap of Healing Time
- 1. Weakest Link Suture/Tendon Interface
- 2. More "lateral" Suture is better then Medial Fixation Point
- 3. Small difference in knot configuration Locking best [Rip-stop]





#### **New Concepts on Using the Natural Biomechanics**



#### Biomechanical Evaluation of Transosseous Rotator Cuff Repair

#### Do Anchors Really Matter? AJSM 2013

Michael J. Salata,\* MD, Seth L. Sherman,<sup>†</sup> MD, Emery C. Lin,<sup>‡</sup> MD, Robert A. Sershon,<sup>§</sup> BS, Aman Gupta,<sup>§</sup> PhD, Elizabeth Shewman,<sup>§</sup> MS, Vincent M. Wang,<sup>§</sup> PhD, Brian J. Cole,<sup>§</sup> MD, Anthony A. Romeo,<sup>§</sup> MD, and Nikhil N. Verma,<sup>§||</sup> MD *Investigation performed at the Rush University Medical Center, Chicago. Illinois* 



**Figure 5.** Normalized optical cyclic elongation with standard deviation. TOE, transosseous-equivalent group; TO, transosseous group; AT, ArthroTunneler group; ATX, ArthroTunneler X-box group.





**Figure 2.** Suture configurations: (A) transosseous equivalent (TOE), (B) transosseous (TO), (C) ArthroTunneler (AT), and (D) ArthroTunneler X-box (ATX).



**Figure 4.** First-cycle construct excursion with standard deviation. \*The excursion for the ArthroTunneler (AT) group was significantly larger than that for the transosseous-equivalent (TOE) group. TO, transosseous group; ATX, ArthroTunneler X-box group.



Conclusion: This study demonstrates that anchorless repair techniques using transosseous sutures result in significantly lower failure loads than a repair model utilizing anchors in a TOE construct.



**Figure 6.** Maximum load to failure with standard deviation. \*The transosseous-equivalent (TOE) group exhibited a statistically greater maximum load than the transosseous (TO), ArthroTunneler (AT), and ArthroTunneler X-box (ATX) groups.







Comparison of Passive Stiffness Changes in the Supraspinatus Muscle After Double-Row and Knotless Transosseous-Equivalent Rotator Cuff Repair Techniques: A Cadaveric Study

Taku Hatta, M.D., Ph.D., Hugo Giambini, Ph.D., Alexander W. Hooke, M.A., Chunfeng Zhao, M.D., John W. Sperling, M.D., Scott P. Steinmann, M.D., Nobuyuki Yamamoto, M.D., Ph.D., Eiji Itoi, M.D., Ph.D., and Kai-Nan An, Ph.D.

Arthroscopy 2016







# **RCR have trouble healing!**

## • Recurrent defects after rotator cuff repair:

**50-89%** 

open:

Harryman et al, JBJS 1993

arthroscopic:

Galatz, Yamaguchi et al, JBJS 2004

**<u>Tissue Failure</u>** Anchor, Knot, Suture Intact



Goals arthroscopic transosseous rotator cuff repair: 1)maximize mechanical integrity 2)maximize biologic healing 3)minimize surgical morbidity, improved outcomes

## RCR Failures: Tissue Quality

## Fatty Infiltration vs Cuff Integrity

- 38 patients with rotator cuff repair
- 70% of patients with >50% fat infiltration had re-torn
- Healed tears demonstrated minimal progression in fatty infiltration
- Failed repair had significantly greater progression
- Outcome scores increased in majority



Gladstone et al, AJSM, 2007

## RCR Failures: Size of Tear



Outcome of arthroscopically repaired large and massive tears

- 18 patients s/p arthroscopic repair of large/massive tears
- Ultrasound evaluation at 12 and 24 months
- Recurrent tears in 17 of 18 patients
- 16 patients had ASES scores increase 48 to 84 points
- At 2 years: only 12 with ASES score >80
- <u>High recurrence of tears however excellent pain relief</u>



Galatz et al, JBJS 2004

Keener et al, ASES open meeting 2010

## The Bigger the Tear – Less Likely to Heal

- 19 shoulders prior rotator cuff repair
- 10 complete tear of single tendon
- 11 both supraspinatus and infraspinatus
- Ultrasound at 1 year
- 2 year F/U
- 70% of single tendon repairs intact
- <u>27% of two tendon repairs intact</u>
- However VAS pain, ASES and active motion improved





#### Waltrip et al AJSM 2003; Apreleva et al Arthroscopy 2001

#### How does Transosseous Facilitate Improvements

- Maximize amount of suture
- Maximize Bleeding
  - Decortication
  - Bleeding at tunnel site
- Transosseous fixation:
   increase mechanical strength
   increase footprint

? increase biologic healing





# However, Clinical Significance has not been as obvious – *Cost Difference!!*

Brady et al- Arthrosco
Double Row
Kim et al-AJSM 2006 – gap formation
Ma et al JBJS 2006 – D





#### on superior with

#### h and decreased



Maximize Suture with minimal footprint "Cost"



#### Foot Print Coverage – Tendon/Suture Contact

3.2mm Bone Tunnel



#### 5.5mm Anchor



6 Passes



Neal S. ElAttrache MD and Thay Q. Lee PhD Los Angeles, CA

An arthroscopic "transosseous-equivalent" rotator cuff repair employing suture-bridges can provide significantly <u>more strength and equal gap formation</u> over a repaired rotator cuff footprint when compared to a double-row technique.







## Reestablishing an Area of Contact

Healing Strength



## **Better Biomechanics – Load Sharing**

#### Increased Load Sharing with Rotation using Lateral Row Repair Technique



better load-sharing

## **"Tension Band" Effect**

#### New Concepts on Using the Natural Biomechanics



#### Repair Failure – Bone Quality Is Important



70 y/o Female with Osteopenia



Note: suture and anchor intact tendon failure

#### Repair Failure – Bone Quality Is Important





#### **Biceps Groove**

## Clinical Case Example – Bone Stock Quality

## 65y/o Female with prior RCR

- **Retained Implant**
- Large Posterior Cyst

- **Options:**
- Place implants around current
- Use larger implant (pullout strength)
- Use Open with traditional Bone Tunnel
- Transosseous Repair







## Clinical Case Example: Failed RCR



#### 58 y/o male with prior RCR





1.5 years out from prior 2 anchor RCR

#### Large Bone cyst, Non-Metal Anchors

## Advantages – Only anchor is Lateral









## Advantages – Pull out Angle







#### Biomechanics As good as TWO 6.5mm Metal Anchors



## Transosseous technique gives more compression



The device use a transosseous tunnel to avoid the direct contact between bone and sutures





## Cadaver Testing Model of Repair

## Implanting the Sharc –FT using the Taylor Stitcher



Biomechanical evaluation of an arthroscopic transosseous anchor as a revision option for rotator cuff repair.

Cadaver Model Matched Pairs Age >65 Samples with similar bone density (Osteopenia condition)

Comparison to two - 6.5 Metal Anchors

Tests native and "revision" condition

Purpose: Biomechanically evaluate an arthroscopic transosseous repair system as a procedure for rotator cuff revision in providing equivalent fixation strength after suture anchor pullout.



#### Footprint Preparation – Aggressive decortication



# Preparation of Samples - Technique

#### Setting up the Taylor Stitcher



#### Setting up the Taylor Stitcher



# Preparation of Samples - Technique

#### Shuttle Sutures – 2 tunnel, 2 suture per tunnel



## **Repair Technique**





Tight Sutures – Finished Repair

### Sharc-Device vs Anchor a biomechanical Compaison





SKIES





### Creating the Defect

## **Repair Technique**



#### Repair the Defect with Sharc - FT





### Guided Passage of "memory" preformed needle



## **Repair Technique**



#### Shuttle Suture within Tunnels



## **Repair Technique**





#### Repair the Defect with Sharc – FT Final Construct






#### Failure Modes





#### Revision Repair with Sharc - FT











#### **Footprint coverage**



#### Footprint-Reconstruction





#### The transosseous approach with SHARC-FT is able to produce a foot print contact area comparable to suture bridge approach





#### Displacement





#### Stiffness of Construct



HUSKIES

#### Peak Load at Failure (Strength of repair)



HUSKIES



#### Lower Bone Density (Reduced Anchor Pull out Strength)

Osteoporotic Bone Disuse osteopenia (Revision RCR)

#### **Multiple Fixation Points**

Smaller Medial bone tunnels (3.2mm) Multiple Suture (Failures occur at Suture – Tendon interface)



#### **Revision RCR Uses Different Fixation Vector**







#### **Central Column of Bone**

Lateral Column of Bone

KIES

#### Advantages- Versatility/Suture Passages

## CONN

#### Suture Number Determines Strength of Rotator Cuff Repair

Patrick W. Jost, MD, M. Michael Khair, MD, Dan X. Chen, MS, Timothy M. Wright, PhD, Anne M. Kelly, MD, and Scott A. Rodeo, MD

Investigation performed at the Sports Medicine and Shoulder Service, Hospital for Special Surgery, New York, NY









#### **Number of Sutures Matters**





Advantages - Biology

#### CURRENT CONCEPTS REVIEW Augmentation of Tendon-to-Bone Healing

Kivanc Atesok, MD, MSc, Freddie H. Fu, MD, DSc, DPs, Megan R. Wolf, BS, Mitsuo Ochi, MD, PhD, Laith M. Jazrawi, MD, M. Nedim Doral, MD, James H. Lubowitz, MD, and Scott A. Rodeo, MD



#### Ability to aggressively remove the cortical Bone – Stimulate Blood Flow











250-750 per implant

1 implant – 6 suture construct

#### Thank you -















### LET'S MEET WHERE THE CONTINENTS MEET ISTANBUL 2014 17-20 SEPTEMBER

# Gap formation in a transosseous rotator cuff repair as a function of bone quality

de C

Β̈́Ε



M. Mantovani<sup>1</sup>, Baudi P<sup>2</sup>, Paladini P<sup>3</sup>, Pellegrini A<sup>4</sup>, Verdano MAc<sup>4</sup>, Porcellini G<sup>3</sup>, Catani Fc<sup>2</sup>

#### Introduction

The transosseous approach has been well known for a long time as a valid repair approac.

Over time various criticisms have been raised over this technique principally classifiable in two main categories: technical difficulty and related reproducibility in an arthroscopic environment, and repair stability (in the suture-bone contact area).



So far the basic drivers for an optimal repair have already been identified and still today these represent the state of the art; between these Burkhart et al. found an optimal cyclic resistance for the avoidance of an excess tension in the repair and the need to look for a more distal area to the proximal metaphyseal. Although a significant discrepancy is evident in both the way measurements are done and the final results provided, gap formation during cyclic loading is a fundamental parameter to be controlled in order to improve the quality and efficacy of the repair .

From a literature survey it is evident that there is an absence of a sufficiently shared test protocol that adopts an objective way to assess gap formation and how the test dynamics influence the final result. An accepted and shared evaluation method would permit to objectively know when the transosseous approach is a suitable solution and transform the approach into a less sensitive repair method to the test conditions.

The aim of this study is to monitor gap formation in a cyclic test set up as  $^{10}$  described below.

#### Materials and Methods

The performance (measured as gap formation) has been monitored as a function  $^{\circ}$  of bone density to verify the effect of the latter.

The test blocks have been shaped by sawbones® test bricks (Malmo, Sweden) of different densities and the following values have been tested: 10, 15, 20, 30, 40 pcf (the grade designation refers to the nominal density of the foam, as indicated in ASTM F1839).

In order to avoid any fault in the gap formation measurement we decided to eliminate the knot tension variable. We conceived special grip equipment to firmly hold the sutures and avoid them from sliding movements and at the same time permit application of the same pre-tension load in all cases without Three different configurations tested in a cyclic mode: pure transosseous (red), transosseous with SHARC-FT in a non closed loop configuration (blue) and transosseous with SHARC-FT with a closed loop backword (green).



Effect of pure transosseous repair approach at the bone-suture interface: catastrofic bone cut at the first cycle in a 10 pcf test block (left), transosseous entry hole modification after 200 cycles in a 15 pcf (middle) and 20 pcf (right) test specimen.

#### introducing superficial damages.





4 2 0 10pcf 15pcf 20pcf 30pcf 40pcf

Gap formation in the 3 tested configuration as a function of bone density.

#### **Experimental results and conclusions**

By comparing measured average displacement as a function of test block density it is evident that there is a significant reduction of their values proportionally to the increase of block density.

The measured span range shifting from 10 to 40 pcf demonstrates a low reproducibility of the repair and how this is strongly affected by the bone consistency; we can therefore state that the construct stability (in term of repair stiffness, ultimate load to failure and gap formation) is affected by bone quality and to guarantee a successful result it seems necessary to know the bone quality before taking the repair decision.

On the basis of our experimental experience an effective way to mitigate this variability effect may be an increase of the sutures number that are passed in the tunnel in order to reduce the specific tension for each.

The suture-bone contact area seems to be the principal source of gap formation in a dynamic test configuration.

The four closing screws have been closed to a constant torque of 12 Nm in all test runs to avoid strand slippage in pre-test constant conditions.

The loading conditions were as follow: oscillating sinusoidal wave form from a minimum of 10N up to 100N and a test frequency of 0,2Hz. A pre-tension of 10N was applied for 1 minute before starting the dynamic test and at 500 repetitions the test was stopped.

The initial displacement was zeroed after this pre-load and the sampling frequency was 100Hz.

The test end was reached when one of these two events occurred: load cycle number 500 was reached or a displacement of the vertical actuator exceeded 10 mm.

With each test block (constant density) we repeated the test five times and the average displacement value and standard deviation were calculated. To reproduce the transosseous repair two different approaches were used: the first is the traditional transosseous method while the second made use of a new device named Sharc-Ft® (NCS lab srl, Modena, Italy. The latter technique uses a titanium device in a transosseous approach to be able to isolate the direct impingement between sutures and synthetic boneThe tested configurations with the various block densities are 3: traditional transosseous approach with 2 high resistance sutures (configuration 1), Sharc-Ft® with two sutures in the tip (configuration 2) and Sharc-Ft® with two sutures in the tip folded back in a closed ring (configuration 3). A failure analysis of the test block was conducted to analyze which are the areas affected by superficial damage and therefore source of gap formation.

1 – NCS lab srl, Carpi (Modena), Italy

2 - Department of Orthopaedic Surgery, Policlinico Modena University 3 - From our failure investigation conducted over the tested samples we can clearly show the reshaped areas (areas where the original tunnel geometry was different); these are principally in the following spots: lateral entry hole and internal area (where the sutures come in contact with the bone).

The experimental evidence of this work is that by avoiding a direct impingement we significantly reduce the gap formation during the test.

This conclusion was obtained also by Salata et al. that shows how the **performance improvement** could be obtained by introducing one or more devices isolating the direct contact with the bone.

This trend, intended as gap formation, was also confirmed making use of an interposed device.

Of great importance however is the chosen suture configuration that can maximize, when the closed ring is recreated (as indicated in configuration 3), the stability of the construct through an optimal force balance and an overall reduction of gap formation (compared to what measured in configuration 2 in which the sutures are loaded only on the tip).

By selecting therefore the test configuration 3 we are able to reproduce a construct which is by far more reproducible varying the test bone density.





Milan February 7th 2017

## Why and when the TO approach is a viable solution? My view Claudio Chillemi



stituto

Chirurgico Ortopedico

Traumatologico

Latina - Italy



TO approach: why?

#### **Tendon – to – bone healing**



## → from the bone→ from the bursa







TO approach: why? **Tendon – to – bone healing**  $\rightarrow$  from the bone  $\rightarrow$  from the bursa COLD **TransOsseous repair** ALITY CONTROL VERIFIED The Biology



**TO approach: when?** 

#### **RCT tear**



@ partial
@ small full-thickness (C1 Snyder classification)
@ moderate/large (C2-C3 Snyder classification)





TO approach: which technique?

**TransOsseous** 



## @ pure (single / double or more tunnels)@ augmented







TO approach: Why? When? Which technique?









#### The eight shape technique





Arthroscopic transosseous rotator cuff repair: the eight-shape technique

Claudio Chillemi<sup>1</sup> · Matteo Mantovani<sup>2</sup> · Marcello Osimani<sup>3</sup> · Alessandro Castagna<sup>4</sup>

Eur J Orthop Surg Traumatol 2017



#### The eight shape technique









2 parallel TO tunnels2 PDS-0 shuttle wires



#### The eight shape technique





The 2 shuttle wires are passed through the medial portion of the tendon stump



#### The eight shape technique





The 2 shuttle wires drag the tape through the tendon into the TO tunnels...



#### The eight shape technique





#### ...like a reverse U





#### The eight shape technique







what happens pulling a traction on the wires



#### The eight shape technique





## The knot is tied on the lateral aspect of the GT







#### The eight shape technique



The extremities of the sutures are then passed laterally through the

tendon





#### The eight shape technique





## The figure of eight is completed (tying the knot laterally on the tendon)



TO approach: when?

#### TransOsseous repair: pure

#### The eight shape technique



#### **RCT tear**

@ partial

@ small full-thickness (C1 Snyder classification)

@ moderate/large (C2-C3 Snyder classification)



TO approach: when?

#### TransOsseous repair: pure

#### The eight shape technique



#### **Tricks: Trans-tendon**









The figure of eight is not completed



TO approach: when?

#### TransOsseous repair: pure

#### The eight shape technique



**Tricks: Trans-tendon** 

@ partial

@ small full-thickness (C1 Snyder classification)

@ moderate/large



der classification)



TO approach: when?

#### TransOsseous repair: pure

#### The eight shape technique





#### **Osteopenia of the HH**



#### Cheese grating effect



#### **TransOsseous repair: augmented**



#### The Elite approach – 2 MC configuration suture



#### Arthroscopic Trans-Osseous Rotator Cuff repair

Claudio Chillemi and Matteo Mantovani

MLT Journal 2017



#### **TransOsseous repair: augmented**

#### The Elite approach – 2 MC configuration suture



1 TO tunnel

- 1 PDS-0 shuttle wire
- **3 pairs of sutures**
- 1 Elite (the implant)


# The Elite approach – 2 MC configuration suture



**Trick:** to avoid any sliding of the wires perform 2 simple knots for each suture





# The Elite approach – 2 MC configuration suture





All the six stitches are then passed through the cuff



# The Elite approach – 2 MC configuration suture





Firstly close the limb 2 with 3 (suture 1), and later the limb 4 with 5 (suture 2) leaving free the limbs 1 and 6



# The Elite approach – 2 MC configuration suture



After cutting respectively one of the end of suture 1 and 2, shuttle from ant to post in the external eyelet of the Elite the limb 1 and the remaining end of

suture 1





# The Elite approach – 2 MC configuration suture



closed loop configuration

*Tie the knot (laterally) between the limbs 1 and 6, and the remaining limb of suture 1 and 2* 





# The Elite approach – 2 MC configuration suture



### When?

# **Osteopenia of the HH**



Association of osteopenia of the humeral head with fullthickness rotator cuff tears

Dominik C. Meyer, MD,<sup>a</sup> Sandro F. Fucentese, MD,<sup>a</sup> Bruno Koller, PhD,<sup>b</sup> and Christian Gerber, MD,<sup>a</sup> Zürich and Bassersdorf, Switzerland

I Shoulder Elbow Surg 2004;13:

tendon tears are associated with a reduction in cancellous bone density of greater than 50%, leading to a



# The Elite approach – 2 MC configuration suture



When?

**Osteopenia of the HH** 

*Tricks:* evaluation of the lateral cortex with a spine needle



# The Elite approach – 2 MC configuration suture



# When? Particular cases







# The Elite approach – 2 MC configuration suture

### When? RC re-tear or non-healing







# The Elite approach – 2 MC configuration suture

# When? Iathrogenic complications

# Complications Observed Following Labral or Rotator Cuff Repair with Use of Poly-L-Lactic Acid Implants

L. Pearce McCarty III, MD, Daniel D. Buss, MD, Milton W. Datta, MD, Michael Q. Freehill, MD, and M. Russell Giveans, PhD



J Bone Joint Surg Am. 2013;95:507-11







# The Elite approach – 2 MC configuration suture

### When?

# GT cyst (associated with RCT)



Arch Orthop Trauma Surg (2013) 133:81-85 DOI 10.1007/s00402-012-1620-6

ARTHROSCOPY AND SPORTS MEDICINE

Footprint reconstruction in a rotator cuff tear associated cyst of the greater tuberosity: augmented anchorage

L. K. Postl · V. Braunstein · R. von Eisenhart-Rothe · C. Kirchhoff

Open surgery Bone void filler: Norian





# The Elite approach – 2 MC configuration suture When? GT cyst (associated with RCT)









### Take home message

# **Evolution in the surgical treatment**







### Take home message

## **Evolution in the surgical treatment**









# c\_chillemi@libero.it



1 2 2	
3 4	
5	Ultrasound and clinical evaluation of massive rotator cuff tear repair using
6	transosseous sharc-ft technique at 6 months follow up
7	
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9	A. Pellegrini, M.A. Verdano, D. Aliani, A. Pesci, F. Ceccarelli, M. De Filippo
10	Orthopaedic and Trauma Department, Parma University Hospital, Parma
11	<sup>°</sup> Radiology Department, Parma University Hospital, Parma
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29	Corresponding Author
30	Pellegrini A., MD
31	Orthopaedic and Trauma Department
32	Parma University Hospital
33	Via Gramsci, 14
34 25	Parma, Italy
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#### 38 Introduction

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Despite rotator cuff repair techniques have evolved significantly in last decade, pushed by the 40 41 progress in technology and materials, rotator cuff re-tears is still a big challenge for shoulder 42 surgeons. Many authors have already analyzed the percentage of re-tear in massive rotator cuff 43 repair showing a lower clinical outcome for this group of patients (Miller 2010). 44 Miller et al have divided re-tears in two different class of failure: early failure (within 3 months 45 post-operative period) reflecting "mechanical" failure; later failure reflecting a biological failure of 46 the healing process (Miller 2010). 47 Recently (Park et al 2013) have confirmed the better outcome of suture bridge (transosseous 48 equivalent) technique in massive rotator cuff repair reporting a lower percentage of re-tears at 6 49 months and a better follow up in comparison to what reported by Miller in a previous study. 50 Transosseous repair technique of rotator cuff repair, in particular with the use of sharc-ft device, has 51 already been studied from a biomechanical stand point showing better biomechanical performance 52 in the extension of foot print coverage and contact pressure (Mantovani et al 2013). 53 Ultrasound has become an important imaging technique in the evaluation of suspected rotator cuff 54 tears and re-tears after surgery. Many studies have shown the good diagnostic performance of 55 ultrasound in the detection of partial and full-thickness tears [1, 2, 3]. (1. Dinnes J, Loveman E, McIntyre L, Waugh N. The effectiveness of diagnostic tests for the assessment of shoulder pain due 56 57 to soft tissue disorders: a systematic review. Health Technol Assess 2003; 7:1 –166 - 2. Teefey SA, Rubin DA, Middleton WD, Hildebolt CF, Leibold RA, Yamaguchi K. Detection and quantification 58

59 of rotator cuff tears: comparison of ultrasonographic, magnetic resonance imaging, and arthroscopic

60 findings in seventy-one consecutive cases. J Bone Joint Surg Am 2004; 86-A:708 –716 - 3. de Jesus

61 JO, Parker L, Frangos AJ, Nazarian LN. Accuracy of MRI, MR arthrography, and ultrasound in the

62 diagnosis of rotator cuff tears: a meta-analysis. AJR 2009; 192:1701 –1707).

63 The aim of this study is ultrasound and clinical evaluations of patients treated with transosseous64 sharc-ft techniques at 6 months follow up looking for possible re-tear in massive rotator cuff repair.

65

#### 66 Materials & Methods

#### 67 <u>Patients</u>

Fifteen consecutive patients who underwent arthroscopic repair for massive rotator cuff tear were enrolled for ultrasound and clinical evaluation after 6 months follow up. All participants had MRI or ultrasound-confirmed full-thickness tears of the rotator cuff before surgery. The indication for surgery was, in all cases, after failure of a non-operative management. All the patients signed informed consent before participating in the study. Tear size satisfying our inclusion criteria (3 cm in greatest dimension) was confirmed at the time of surgery (fig. 1) in all patients under arthroscopic visualization.

75 <u>Surgery</u>

All rotator cuff repairs were performed by 2 experienced shoulder surgeons (M.A.V. – A.P.). All
 procedures were performed with the patient under general anesthesia and supplemented with a
 preoperative interscalene block placed under ultrasound guidance.

Rotator cuff repair was performed using the transosseous technique described by Pellegrini et al
(fig. 2) (Arthroscopy technique in press).

All patients were immobilized after surgery using an abduction sling for 2 weeks (Donjoy Ultrasling III AB 45°, DJ Orthopedics, LLC, Vista, California) and after this initial phase a standardized supervised physical therapy protocol was initiated. Patients were instructed to remove the abduction sling only for daily bathing and dressing needs during the first 2 weeks after surgery,

and passive range of motion, excluding pendulums, was not permitted during this period. The
rehabilitation protocol included passive range of motion from weeks 2 to 6, with active and active-
assisted range of motion thereafter. A focused strengthening program was initiated at week 10.
Ultrasound and clinical evaluation
Diagnostic ultrasound examination was performed at 6 months follow up. All patients underwent
clinical examinations with Constant, Dash and SST scores.
Ultrasound examination was performed using ultrasound scanner (Model iU22 Philips) with linear
high-frequency probe (L12-5 MHz). A tendon was considered not torn if at ultrasonography
continuous and stretched fibers over the humeral head and no alteration of ultrasound signal was
visualized. (Fig. 4-10)
In addition X-ray examination of the shoulder was performed in true AP and axillary projection.
Authors look for osteolytic lesion around sharc-ft device, suggestive for device mobilization. (Fig.
11a-b)

98

#### 99 **Results**

All the enrolled patients completed ultrasound and clinical evaluation at 6 months follow-up. There
were no significant differences in subjects examined in terms of age, tobacco habit or gender.

All the patients underwent subacromial decompression and transosseous sharc-ft repair for massive
rotator cuff tear. Biceps tenotomy was performed in 13 patients while one already have a biceps
rapture before underwent arthroscopy.

105 Data collected are reported in table 1.

106 In ultrasound examinations authors find no case of re-tear at 6 months of follow up confirmed by 107 the good to excellent clinical outcome emerged with the scores collected (table 1). Moreover at X-108 ray examination authors find no osteolytic lesion.

109

#### 110 **Discussion**

111 Massive rotator cuff tears are usually associated with pain, weakness and loss of function. In 112 particular this kind of lesions occur both in heavy worker population as well as sedentary people 113 leading to poor autonomy in daily activities and frequently to an important social cost. Moreover, 114 repair technique for these lesions are usually difficult and associated with a higher re-tear rate.

One report published in 2007 involved a prospective series of 106 patients with rotator cuff tears repaired using a double-row technique (Sugaya 2007); Although the overall re-tear rate was 17%, the re-tear rate in large to massive rotator cuff tears was 40% on MRI. In the same year, the re-tear rate of large to massive tears was reported to be 17% using the double-row technique (La fosse 2007). Huijsmans et al (2007) reported a failure rate in double-row repairs of large to massive cuff tears of 36% on ultrasonography (2007).

121 The above cited studies were performed using arthroscopic double-row repair. On the other hand, 122 several studies have employed arthroscopic suture bridge repair. One study in 2008, 25 patients 123 who had undergone arthroscopic suture bridge repair at a mean follow-up of 14.61 months and MRI 124 resulted in 88% of repairs healed; however, massive tears cases in that study were only 3 (Frank 125 2008).

126 This study is the first in literature evaluating transosseous repair technique with the use of sharc-ft 127 for massive rotator cuff repair; authors opted for using ultrasound examination as previously 128 reported in many papers (Park et al, Miller et al) supported by Codsi (2014). In the community setting, ultrasound may be used to evaluate the integrity of a repaired rotator cuff tendon and
represents a comparable alternative to MRI when evaluating the integrity of a rotator cuff repair.
(Codsi 2014).

132 Both diagnostic ultrasound and magnetic resonance imaging (MRI) are used for investigation of the 133 presence and severity of rotator cuff lesions. There is no consensus as to which is the more accurate 134 and cost-effective study. Shoulder ultrasound has the advantage of being relatively inexpensive and 135 widely available and permits dynamic imaging. However, several papers have reported wide 136 variability in the ability of ultrasound to accurately differentiate between partial thickness and full-137 thickness rotator cuff tears, particularly between observers. (1. Martin-Hervas C, Romero J, Navas-138 Acien A, Reboiras JJ, Munuera L. Ultrasonographic and magnetic resonance images of rotator cuff 139 lesions compared with arthroscopy or open surgery findings. J Shoulder Elbow Surg 2001; 10: 410– 140 15 - 2- Teefey SA, Hasan SA, Middleton WD, Patel M, Wright RW, Yamaguchi K. 141 Ultrasonography of the rotator cuff. J Bone Joint Surg Am 2000; 82: 498–504. - 3 Hodler J, Fretz CJ, Terrier F, Gerber C. Rotator cuff tears: correlation of sonographic and surgical findings. 142 143 Radiology 1988; 169: 791–4).

Rutten MJ et al (2010) refuted the hypothesis that ultrasound of the shoulder is operator-dependent and related to experience. In this study, there was excellent agreement for the detection of rotator cuff tears, which only slightly improved with the increasing experience of the general radiologist. Accuracy of rotator cuff tear detection was high and in accordance with the results in the literature

148 (1- Ultrasound detection of rotator cuff tears: observer agreement related to increasing experience.

149 Rutten MJ, Jager GJ, Kiemeney LA. AJR Am J Roentgenol. 2010 Dec;195(6).

150 The transosseous approach has been known as a valid repair strategy. Over time, various criticisms 151 were made about this technique mainly ascribable to two main categories: technical difficulties 152 mainly related to the reproducibility in an arthroscopic environment and stability of the construct 153 (in the suture–bone contact area).

The authors believe that the problems above described can be solve in a transosseous approach by interposing a device isolating sutures from bone (Sharc-Ft®). With this new approach, a direct impingement is avoided and, in the closed ring configuration, the contact pressure is mitigated and the risk of local bone damage reduced. This also prevents the user to know a priori the value of bone density (Mantovani et al 2014). As reported by Baudi et al (2013), transosseous repair with sharc-ft had good to excellent clinical outcome at one year follow-up but the rate re-tear was not investigated in that study.

161

#### 162 **Conclusion**

163 Results from this study confirmed with the help of ultrasound examination the excellent clinical 164 outcome obtained by our patients. Whilst complying with what reported by previous Authors. 165 Despite of the limited number of subjects, all patients involved in the study were affected by 166 massive rotator cuff, therefore creating a homogeneous group of patients.

167 The arthroscopic transosseous repair technique with sharc-ft shown excellent results in terms of re-168 tear rate confirming the biomechanical advantages of this type of surgical choice.

169

170

171

**References** 

### 174175 Figures

- 176 Fig. 1: an example of large massive rotator cuff tear repaired by authors
- 177 Fig. 2: A sharc-ft device during arthroscopy
- 178 B suture passages during arthroscopic repair
- 179 Fig. 3: A-B arthroscopic view after rotator cuff repair
- 180 Fig. 4: Ultrasound at 6 months follow-up demonstrates regular insertion (arrow) of the supraspinat
- 181 us tendon (SS) over humeral head (HH) and suture (head arrow)
- 182 Fig. 5: Sharc-ft device at ultrasound examination (arrow)
- 183 Fig. 6: Ultrasound at 6 months follow-up demonstrates regular insertion (arrow) of the
- 184 supraspinatus tendon (SS) over humeral head (HH) and suture (head arrow)
- Fig. 7: Little fluid articular effusion (white line) over supraspinatus tendon (SS), after subacromialbursectomy
- 187 Fig. 8 a-b: The image compares right (R) and left (L) shoulder. The left shoulder, undergone a

188 rotator cuff repair using the transosseous technique with Sharc-ft device, show no re-tear of the

- 189 supraspinatus tendon (SS)
- Fig. 9: The suture, three ovalar hyperechoic image (arrow) in this figure, can be mistake withcalcification
- 192 Fig. 10: Ultrasound at 6 months follow-up demonstrates continuity of supraspinatus tendon (SS)
- and its regular insertion (head arrow) upon humeral head (HH). Acromion (Acr)
- 194 Fig. 11 a-b: X-ray in true AP projection in extra-rotation (a) and axillary projection (b) showing

195 clearly no mobilization of sharc-ft device

#### 196

197 Fig 1



#### 203 Fig 2



209 Fig 3





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#### 214 Fig 4



219 Fig 5



224 Fig 6



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232 Fig 7



238 Fig 8



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244 Fig 9







256 Fig 11



264 265	Table
266	Table 1: data collected at the time of follow up
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285	T-OP COMPL		PAIN IN PROXIMA									DE-1 SCAPULAR DIS				
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288	CM SCORE (X/1	<b>5</b> 5	76	87	85	83	82	84	80	81	8	62	82	88	11	82
289	ASES															
	SST (X/12)	12	10	Ц	12	10	6	12	80	10	7	10	6	12	7	1
	ABD	180°	180°	180°	180°	180°	180	180°	180°	170°	180	180°	170°	180°	160°	160°
	ANT FLEX	180°	180°	180°	180°	180°	180°	180°	180°	170°	180°	180°	160°	180°	170°	160°
	ER2	90°	90°	°0	80°	°0	<b>0</b> 0	°0	90°	80°	<b>0</b> 6	°0°	80°	<b>0</b> 0	80°	80°
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	IR ERI ER2	D7 60° 90°	L3 45° 90°	D7 60° 90°	D12 45° 80°	L3 45° 90°	L3 50° 90°	D12 50° 90°	L3 50° 90°	L3 45° 80°	L3 50° 90°	D12 60° 80°	L3 50° 80°	L3 60° 90°	GLUTEUS 45° 80°	GLUTEUS 45° 80°
	FKT (m) IR ER1 ER2	6 D7 60° 90°	4 L3 45° 90°	4 D7 60° 90°	6 D12 45° 80°	5 L3 45° 90°	5 L3 50° 90°	4 D12 50° 90°	4 L3 50° 90°	6 L3 45° 80°	4 L3 50° 90°	5 D12 60° 80°	4 L3 50° 80°	4 L3 60° 90°	6 GLUTEUS 45° 80°	4 GLUTEUS 45° 80°
	F-UP (m) FKT (m) IR ER1 ER2	21 6 D7 60° 90°	20 4 L3 45° 90°	17 4 D7 60° 90°	14 6 D12 45° 80°	13 5 L3 45° 90°	12 5 L3 50° 90°	11 4 D12 50° 90°	10 4 L3 50° 90°	9 6 L3 45° 80°	8 4 L3 50° 90°	7 5 D12 60° 80°	7 4 L3 50° 80°	6 4 L3 60° 90°	5 6 GLUTEUS 45° 80°	4 4 GLUTEUS 45° 80°
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	DOMINANT LIMB CLB TENOTOMY F-UP (m) FKT (m) IR ER1 ER2	NO YES 21 6 D7 60° 90°	YES NO 20 4 L3 45° 90°	NO YES 17 4 D7 60° 90°	YES YES 14 6 D12 45° 80°	YES YES 13 5 L3 45° 90°	YES YES 12 5 L3 50° 90°	NO YES 11 4 D12 50° 90°	NO NO 10 4 L3 50° 90°	YES YES 9 6 L3 45° 80°	YES YES 8 4 L3 50° 90°	YES YES 7 5 D12 60° 80°	NO YES 7 4 L3 50° 80°	YES YES 6 4 L3 60° 90°	YES YES 5 6 GLUTEUS 45° 80°	YES YES 4 4 GLUTEUS 45° 80°
	AGE DOMINANT LIMB CLB TENOTOMY F-UP (m) FKT (m) IR ER1 ER2	54 NO YES 21 6 D7 60° 90°	47 YES NO 20 4 L3 45° 90°	60 NO YES 17 4 D7 60° 90°	54 YES YES 14 6 D12 45° 80°	59 YES YES 13 5 L3 45° 90°	62 YES YES 12 5 L3 50° 90°	51 NO YES 11 4 D12 50° 90°	48 NO NO 10 4 L3 50° 90°	55 YES YES 9 6 L3 45° 80°	68 YES YES 8 4 L3 50° 90°	66 YES YES 7 5 D12 60° 80°	51 NO YES 7 4 L3 50° 80°	47 YES YES 6 4 L3 60° 90°	50 YES YES 5 6 GLUTEUS 45" 80"	54 YES YES 4 4 GLUTEUS 45° 80°
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UNIVERSITA' DEGLI STUDI DI VERONA Clinica Ortopedica e Traumatologica Direttore: Prof. P.Bartolozzi



# Double-row surgical technique in rotator cuff repair



### E. Vecchini – F. Perusi - P. Bartolozzi



# WHAT IS IT ?





Double-row rotator cuff repair techniques incorporate a medial and lateral row of suture anchors in the tear repair configuration.



# **ADVANTAGES**



#### **DOUBLE-ROW technique:**

- Reproducubile
- Anatomical and biomechanical footprint restoration
- Better tendon-bone interface
- Good stabilization
- Tension band function











# SURGICAL TECHNIQUE

Two holes for the anchors are made close to the edge of the articular surface of the humeral head.

> Two double-loaded anchors are inserted to make the FIRST ROW of the double row repair.





# SURGICAL TECHNIQUE

The sutures on the anterior side are passed through the tendon and out through the anterior portal; the same for the posteriors sutures through the posterior portal.

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## SURGICAL TECHNIQUE

This process is repeted with another two suture limbs.





## SURGICAL TECHNIQUE

One suture limb from each anchor set is passed through the superior lateral portal.

















## SURGICAL TECHNIQUE

This process is repeted with the remaining two suture limbs.

The DOUBLE ROW suture is now complete.



#### LITERATURE



#### Meta-analysis

#### Single-Row Repair Versus Double-Row Repair of Full-Thickness Rotator Cuff Tears

Niti Prasathaporn, M.D., Somsak Kuptniratsaikul, M.D., and Kitiphong Kongrukgreatiyos, M.D.

Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 27, No 7 (July), 2011: pp 978-985

#### Clinical Outcome and Imaging of Arthroscopic Single-Row and Double-Row Rotator Cuff Repair: A Prospective Randomized Trial

Hsiao-Li Ma, M.D., En-Rung Chiang, M.D., Hung-Ta H. Wu, M.D., Shih-Chieh Hung, M.D., Ph.D., Shih-Tein Wang, M.D., Chien-Lin Liu, M.D., and Tain-Hsiung Chen, M.D.

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William T. Pennington, M.D., David J. Gibbons, M.D., Brian A. Bartz, P.A.-C., Maggie Dodd, P.T., James Daun, P.T., Jonathan Klinger, B.S., Milodrag Popovich, M.D., and Brian Butler

Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 26, No 11 (November), 2010: pp 1419-1426





# ITERATURE IN SUPPORT OF DOUBLE ROW TECNIQUE

YOUNG PEOPLE

TEARS > 3 cm

#### HIGH FUNCTIONAL NEEDS

The results showed that double-row repair improved tendon healing and provided greater external rotation







Prospective Randomized Clinical Trial of Single- Versus Double-Row Suture Anchor Repair in 2- to 4-cm Rotator Cuff Tears: Clinical and Magnetic Resonance Imaging Results

Kyoung Hwan Koh, M.D., Kyung Chung Kang, M.D., Tae Kang Lim, M.D., Min Soo Shon, M.D., and Jae Chul Yoo, M.D.

Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 27, No 4 (April), 2011: pp 453-462

#### Single-row versus double-row arthroscopic rotator cuff repair in small- to medium-sized tears

Nuri Aydin, MD<sup>a,b,\*</sup>, Baris Kocaoglu, MD<sup>b</sup>, Osman Guven, MD<sup>b</sup>

1058-2746/\$ - see front matter © 2010 Journal of Shoulder and Elbow Surgery Board of Trustees. doi:10.1016/j.jse.2009.11.053





# LITERATURE AGAINST DOUBLE ROW TECNIQUE

#### IMPROVED HEALING ONLY RADIOGRAPHICALLY (MRI)

#### INCREASED OPERATIVE TIME

#### MORE EXPENSIVE

Despite double-row repair shows a significantly higher rate of tendon healing and greater external rotation than does single-row repair, there is no significant improvement in shoulder function, muscle strength, forward flexion, internal rotation, patient satisfaction, or return to work.





#### I USUALLY PREFER THE SINGLE ROW TECNIQUE







### IN MY CLINICAL PRACTICE I USE THE DOUBLE ROW TECNIQUE

## **GREATER TUBEROSITY FRACTURE**













## OFTEN REDUCTION WITH INTERNAL FIXATION IS UNSATISFAYING BACUSE OF ITS MULTIFRAGMENTARITY









- traumatic humeral greater tuberosity fracture
- 3 days after trauma treated arthroscopically with 2 screws using
  DOUBLE-ROW technique (Super Revo®, Linvatec/ Versalok™, DePuy-Mitek)
   21 days rest in Desault brace, after that rehabilitation

























































IN MY CLINICAL EXPERIENCE... IN ROTATOR CUFF LESIONS LARGER THAN 3 cm I USE A MODIFIED DOUBLE ROW TECHNIQUE ASSOCIATED WITH A TRANSOSSEUS SUTURE





BECAUSE OFTEN IN MASSIVE LESIONS WE FIND A POOR BONE QUALITY AND BY THIS WAY THERE IS A HIGH RISK OF <u>SCREW'S PULL OUT</u>





FIGURE 1. (A) Anteroposterior (AP) portable radiograph immediately posioperatively showing repair of a 1-om suprasplinatus ieur in a 77-year-old man. (B) Anteroposterior shoulder radiograph 2 weeks posioperatively showing early metallic suture anchor pullout. (C) Intraoperative arthroscopic image showing the pulled-out anchor still subtred in the failed cut? resair. Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 26, No 3 (March), 2010: pp 310-315

The Incidence of Early Metallic Suture Anchor Pullout After Arthroscopic Rotator Cuff Repair

Eric C. Benson, M.D., Joy C. MacDermid, B.Sc.P.T., M.Sc., Ph.D., Darren S. Drosdowech, M.D., F.R.C.S.C., and George S. Athwal, M.D., F.R.C.S.C.

#### CONCLUSIONS

There is a minimal risk of suture anchor pullout in small- to medium-sized tears; however, this risk increases with larger tear sizes. We recommend routine radiographic follow-up after use of metallic anchors to ensure identification of early failure by anchor pullout.



### **MY MODIFIED DOUBLE ROW**



#### Transosseus suture repair demonstrated superior tendon fixation with reduced motion at the tendon to tuberosity interface



Tendon-bone interface motion in transosseous suture and suture anchor rotator cuff repair techniques.

by Christopher S Ahmad, Andrew M Stewart, Rolando Izquierdo, Louis U Bigliani

Knee Surg Sports Traumatol Arthrosc. 2011 Oct 20. [Epub ahead of print]

#### Arthroscopic transosseous (anchorless) rotator cuff repair.

Garofalo R, Castagna A, Borroni M, Krishnan SG.

Shoulder Service Hospital F. Miulli, Acquaviva delle fonti, BA, Italy, raffaelegarofalo@gmail.com.





I USE FISH-FIT TRANSOSSEUS TECHNIQUE BECAUSE IT PERMITTS TO PERFORM DIFFERENT KIND OF SUTURE CONFIGURATIONS IN RELATION WITH DIFFERENT TYPES OF CUFF LESIONS

















## MY MODIFIED DOUBLE ROW











### **MY MODIFIED DOUBLE ROW**



## <u>Sharc FT</u>

- Great stability with every bone quality
- Higher Pull out force and better fatigue resistance
- Great flexibility fairly independent from lesion dimension
- Minimally invasive
- Easy to use steep learning curve
- Avoid direct interface suture-bone
- More anatomical foot print
- Several possible configurations





### THANK YOU

