Smith+Nephew

Evidencia «in focus»

Advanced Healing Solutions

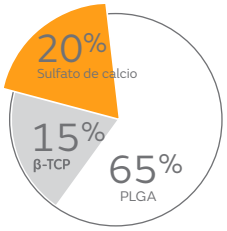
Redefiniendo el potencial de consolidación en la reparación del manguito de los rotadores

Vea la evidencia científica >>

HEALICOIL◊ REGENESORB◊
Anclaje de sutura

HEALICOIL◊ KNOTLESS
Anclaje de sutura

REGENETEN◊
Implante bioinductivo



REGENESORB◊
Material

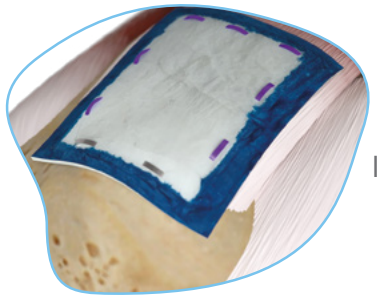
Advanced Healing Solutions: recopilación de evidencia científica

Esta recopilación de evidencia científica resume la evidencia clínica de la cartera de **Advanced Healing Solutions** de S+N:

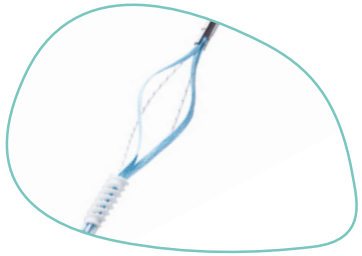
Redefiniendo el potencial de consolidación

para la reparación del manguito de los rotadores

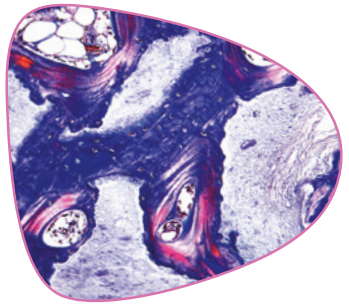
Haga clic para ver la evidencia científica por producto:



REGENETEN◊
Implante bioinductivo



HEALICOIL◊
Anclaje de sutura



REGENESORB◊
Material

Leyenda

- Resultados del estudio de imagen
- Resultados del paciente
- Biopsia
- Biomecánica

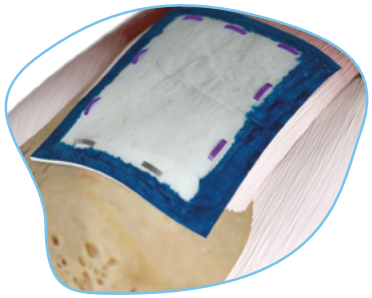
Funcionalidad

- Enlace al resumen completo
- Ver y compartir en Educación + Evidencia científica
- Volver al menú
- Lista de referencias

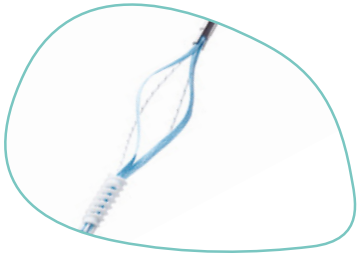
Abreviaturas

3D-FEM = método tridimensional de elementos finitos
ASES = American Shoulder and Elbow Surgeons
FT = espesor total
DMCI = diferencia mínima clínicamente importante
RM = resonancia magnética
PT = espesor parcial
RMR = reparación del manguito de los rotadores
SANE = evaluación numérica de valoración individual
SS = supraespinoso
VR-12 PCS = Encuesta de salud a veteranos RAND de 12 elementos (VR-12), puntuación del componente físico
WORC = índice de Western Ontario para el manguito de los rotadores

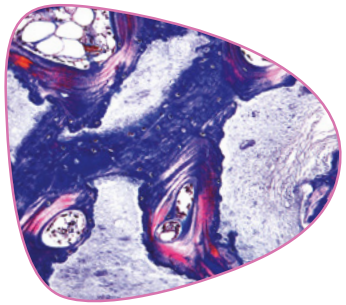
Advanced Healing Solutions: recopilación de evidencia científica



REGENETEN◊
Implante bioinductivo

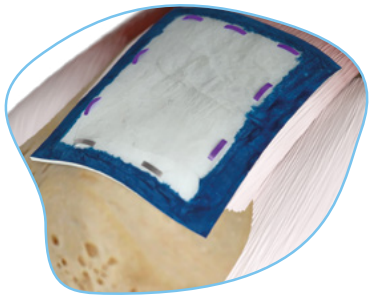


HEALICOIL◊
Anclaje de sutura



REGENESORB◊
Material

Advanced Healing Solutions: recopilación de evidencia científica



REGENETEN◊
Implante bioinductivo

HEALICOIL◊
Anclaje de sutura

REGENESORB◊
Material

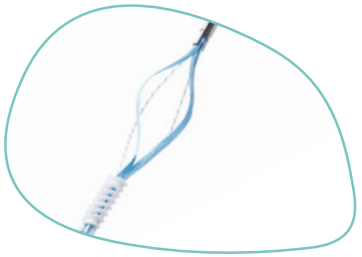
Cambiando el curso de la patología del manguito de los rotadores

El implante bioinductivo REGENETEN estimula la respuesta de curación natural del organismo para apoyar el crecimiento del nuevo tendón e interrumpir la progresión de la enfermedad.[1,2]

Autor	Hallazgo clave	Tipo de desgarro				
Evidencia científica clave						
Arnoczky SP, et al.	El implante bioinductivo REGENETEN◊ es absorbido rápidamente y reemplazado por tejido similar a tendón en el plazo de seis meses[3]	FT			✔	
Bokor DJ, et al.	La mejora en el espesor del tendón y la integridad se mantuvieron cinco años después del tratamiento con el implante bioinductivo REGENETEN◊[4]	PT	✔	✔		
Schlegel TF, et al.	El implante bioinductivo REGENETEN◊ induce la formación de tejido similar a nuevo tendón en pacientes con roturas de espesor parcial del tendón supraespinoso[2]	PT	✔	✔		
Thon SG, et al.	El implante bioinductivo REGENETEN◊ promueve la inducción de tejido y tasas elevadas de consolidación del tendón en pacientes con roturas grandes y masivas del manguito de los rotadores[5]	FT	✔	✔		
Evidencia científica de apoyo						
Bokor DJ, et al.	El implante bioinductivo REGENETEN◊ mantiene la integridad de la reparación en roturas del manguito de los rotadores de espesor completo[6]	FT	✔	✔		
Mcintyre LF, et al	Mejoras clínicamente relevantes en el dolor y la funcionalidad en un estudio multicéntrico de registro del implante bioinductivo REGENETEN◊ en la reparación del manguito de los rotadores[7]	Ambos		✔		

Advanced Healing Solutions: recopilación de evidencia científica

REGENETEN◊
Implante bioinductivo



HEALICOIL◊
Anclaje de sutura

REGENESORB◊
Material

Arquitectura abierta: Abiertos a mejores posibilidades

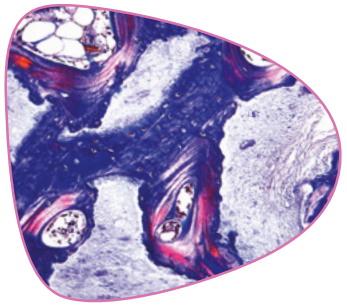
El diseño de estructura abierta de los anclajes HEALICOIL reduce la cantidad de material implantado en el hombro, en comparación con los anclajes macizos tradicionales y puede proporcionar una ventaja en la consolidación biológica.[8]

Autor	Hallazgo clave	Tipo de desgarro				
Evidencia científica clave						
Chahla J, et al.	Una densidad ósea significativamente mayor rodeando los anclajes de sutura HEALICOIL◊ PK en comparación con los anclajes de sutura TWINFIX◊ PK seis meses después de la RMR[9]	FT	✔	✔		
Clark TR, et al.	El espesor del manguito de los rotadores fue significativamente mayor a las seis semanas en pacientes que recibieron anclajes de sutura fenestrados en comparación con los anclajes de sutura no fenestrados[8]	FT	✔			
Evidencia científica de apoyo						
Kim J-H, et al.	Crecimiento de hueso significativamente mejorado con los anclajes de sutura HEALICOIL◊ PK en comparación con los anclajes de sutura TWINFIX◊ HA seis meses después de la reparación del manguito de los rotadores[10]	Ambos	✔	✔		
Sano H, et al.	Las propiedades de fijación, la distribución de la tensión y los patrones de fallo difieren entre los anclajes de sutura de tipo espiral y de tipo tornillo para la reparación del manguito de los rotadores[11]	N/A				✔

Advanced Healing Solutions: recopilación de evidencia científica

REGENETEN◊
Implante bioinductivo

HEALICOIL◊
Anclaje de sutura



REGENESORB◊
Material

Una formulación única de materiales probados

El material REGENESORB se ha diseñado para empezar con ventaja en la formación de hueso y la curación ósea, y se reabsorbe y reemplaza por hueso en un plazo de 24 meses.[12]

Autor	Hallazgo clave	Tipo de desgarro	
Evidencia científica clave			
Vonhoegen J, et al.	El anclaje de sutura HEALICOIL◊ REGENESORB se reabsorbió en su mayor parte y fue reemplazado por material óseo nuevo en los 21 meses siguientes a la reparación artroscópica del manguito de los rotadores[13]	FT	✔
Comparación con los competidores			
Vonhoegen J, Sgroi M.	Comparación de la reabsorción de los anclajes HEALICOIL REGENESORB y los anclajes biocompuestos Arthrex	FT	✔

El implante bioinductivo REGENETEN◊ es absorbido rápidamente y reemplazado por tejido similar a tendón en el plazo de 6 meses

Arnoczky SP, et al. *Arthroscopy* (2017)[3]

Descripción general

- Estudio retrospectivo de biopsias tomadas de 7 pacientes (6 roturas de espesor completo, 1 rotura de espesor parcial) entre 5 semanas y 6 meses tras la RMR aumentada con el implante bioinductivo REGENETEN

Resultados

- Rápido crecimiento de células huésped y formación temprana de colágeno observados a las 5 semanas
- Mayor formación de colágeno, maduración y organización en la superficie del implante a los 3 meses (figura 1)
- A los 6 meses, el implante ya no era visible, con nuevo tejido similar a tendón y colágeno altamente orientado, indicativo de carga funcional (figura 2)

Conclusiones

En una serie de biopsias de revisión, el implante bioinductivo REGENETEN se reabsorbió y reemplazó por tejido nuevo rápidamente. Los seis meses después de la cirugía, el nuevo tejido era similar a tendón con colágeno orientado, indicativo de carga funcional.

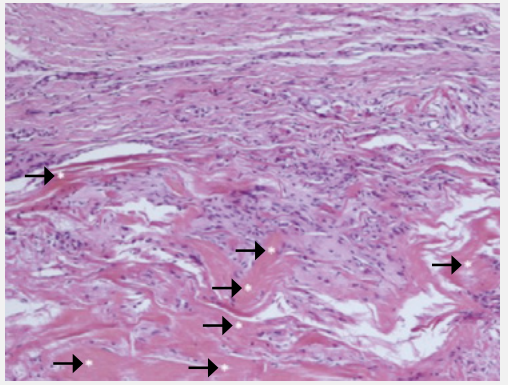


Figura 1. Microfotografía de la superficie del implante a los 3 meses. Restos del implante aún presentes (→) (hematoxilina-eosina x 100)

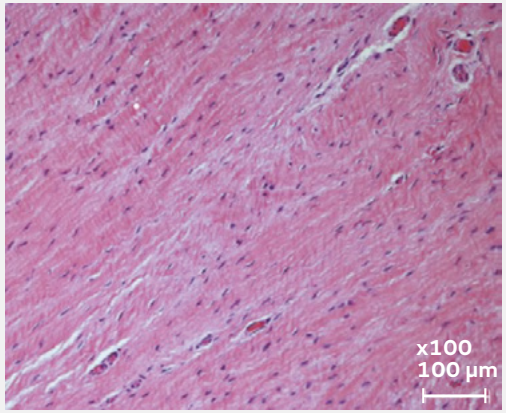


Figura 2. Microfotografía de la superficie del implante a los 6 meses. No hay evidencia científica de restos del implante (hematoxilina-eosina x 100)

El implante bioinductivo REGENETEN◊ mantiene la integridad de la reparación en roturas FT del manguito de los rotadores

Bokor DJ, et al. *Muscles Ligaments Tendons J* (2015)[6]

Descripción general

- Estudio prospectivo de 9 pacientes con roturas del tendón supraespinoso (8 roturas FT de tamaño medio, 1 rotura PT convertida en FT durante la cirugía) que recibieron el implante bioinductivo REGENETEN junto con una reparación estándar

Resultados

- La RM no mostró evidencia científica de nuevas roturas o discontinuidades a los 24 meses
- Espesor promedio del tendón significativamente mayor en la RM en los pacientes del estudio frente a los valores publicados de adultos jóvenes sanos; el espesor se mantuvo hasta los 24 meses (p<0,01; figura)
- No fue posible distinguir el tejido nuevo del tendón nativo en la RM de los 12 meses
- Mejoras significativas en la puntuación ASES y la puntuación Constant-Murley a los 24 meses en comparación con los valores preoperatorios (p<0,001 en ambos casos)

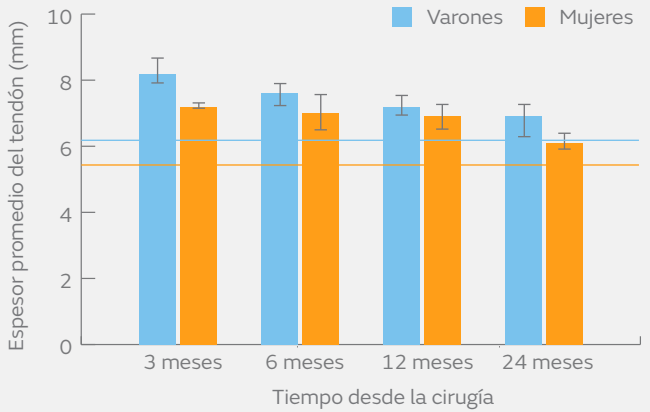


Figura. Media (± error estándar) de espesor del tendón en pacientes varones (n=6) y mujeres (n=3) en comparación con los espesores normales promedio publicados (líneas horizontales) en varones y mujeres sanos; p<0,01 en todos los puntos temporales

Conclusiones

El implante bioinductivo REGENETEN facilita la restauración de la superficie normal del tendón y mantiene la integridad de la reparación de las roturas FT durante 24 meses.

Disponible en: Muscles, Ligaments and Tendons Journal

El implante bioinductivo REGENETEN◊ induce la formación de tejido tendinoso en pacientes con roturas de PT del tendón supraespinoso (SS)

Schlegel TF, et al. *J Shoulder Elbow Surg* (2017)[2]

Descripción general

- Estudio multicéntrico prospectivo de 33 pacientes con roturas PT del tendón supraespinoso que recibieron el implante bioinductivo REGENETEN tras una descompresión subacromial sin reparación

Resultados

- Reducción en el tamaño de la rotura ≥en 1 grado con respecto al valor inicial en 31/33 pacientes (94 %) al cabo de 1 año
  - 8/33 pacientes (24 %) no tuvieron ningún defecto visible
- Aumento significativo del espesor promedio del tendón en la RM al año frente a los valores preoperatorios (p<0,0001; figura)
- Mejoras significativas en las puntuaciones de dolor de la ASES, de índice del hombro de la ASES y de Constant-Murley desde el inicio del estudio hasta 1 año (p<0,0001), de más del doble de las DMCI correspondientes
- Al año, 30/33 pacientes (94 %) se mostraron satisfechos con los resultados de la intervención

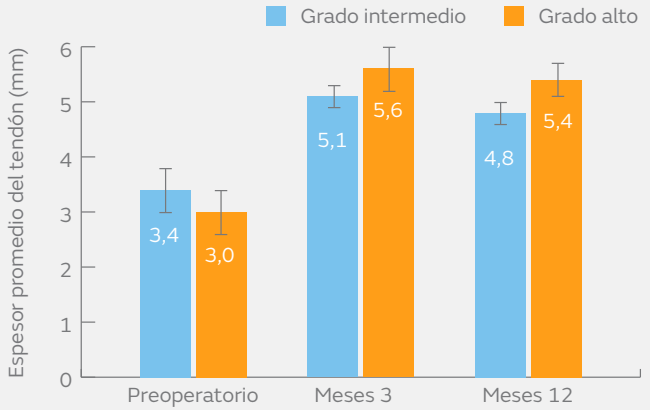


Figura. Espesor promedio del tendón (± error estándar) en la RM en roturas de grado intermedio y alto.

A los 12 meses, p=0,003 y p<0,0001 para roturas de grado intermedio y alto, respectivamente, con respecto a las medidas preoperatorias

Conclusiones

El implante bioinductivo REGENETEN aumenta biológicamente la consolidación, mejorando el espesor del tendón y reduciendo el tamaño de la rotura. Los pacientes comunicaron mejoras en la función, una alta satisfacción y una recuperación rápida.

El implante bioinductivo REGENETEN◊ produce la inducción de tejido y tasas elevadas de consolidación del tendón en roturas grandes y masivas del manguito de los rotadores

Thon SG, et al. *Am J Sports Med* (2019)[5]

Descripción general

- Estudio prospectivo de 23 pacientes (edad media, 57,9 años) que reciben un implante bioinductivo REGENETEN junto con una reparación en doble fila de roturas del manguito de los rotadores grandes (n=11) o masivas (n=12)

Resultados

- No hubo acontecimientos adversos relacionados con el implante
- Curación del tendón en 22/23 pacientes (96 %) en una ecografía a los 24 meses
- Éxito del tratamiento en 21/23 pacientes (91 %) a los 24 meses; un fracaso clínico adicional debido a la progresión de la artrosis glenohumeral (figura)
- El espesor medio del tendón en una ecografía aumentó de 6,29 mm a los 3 meses a 7,72 mm a los 12 meses, y disminuyó a 7,28 mm a los 24 meses

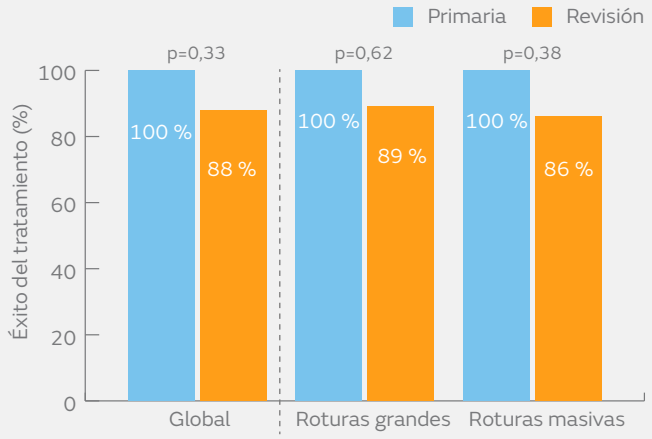


Figura. Porcentaje de pacientes con éxito del tratamiento en reparaciones primarias y de revisión

Conclusiones

En combinación con la reparación de roturas del manguito de los rotadores grandes y masivas, el implante bioinductivo REGENETEN fue seguro, indujo la formación de tejido y se asoció a una tasa de consolidación del tendón alta tanto en casos primarios como de revisión.

La mejora en el espesor del tendón y la integridad se mantuvieron cinco años después del tratamiento con el implante bioinductivo REGENETEN◇

Bokor DJ, et al. *Muscles Ligaments Tendons J* (2019)[4]

Descripción general

- Cinco años de seguimiento de un estudio prospectivo con un solo grupo para evaluar el implante bioinductivo REGENETEN en lugar de la reparación en pacientes con roturas del manguito de los rotadores de PT
- 11/13 pacientes inscritos estuvieron disponibles para la evaluación a los 5 años

Resultados

- 8/11 pacientes (73 %) no mostraron pérdida de la integridad del tendón entre 2 y 5 años (figura)
- El espesor del tendón medio disminuyó significativamente entre 2 y 5 años (5,9 frente a 5,2 mm; p=0,0012), pero siguió siendo significativamente mayor que los valores preoperatorios (4,3 mm; p<0,0001)
- Las mejoras significativas frente al inicio del estudio en el dolor y la funcionalidad se mantuvieron hasta 5 años (p≤0,01) y no fueron significativamente distintos de los valores obtenidos a los 2 años

Conclusiones

El implante bioinductivo REGENETEN mostró una eficacia sostenida para mejorar la integridad y el espesor del tendón, sin reducción en el dolor y la funcionalidad entre 2 y 5 años.

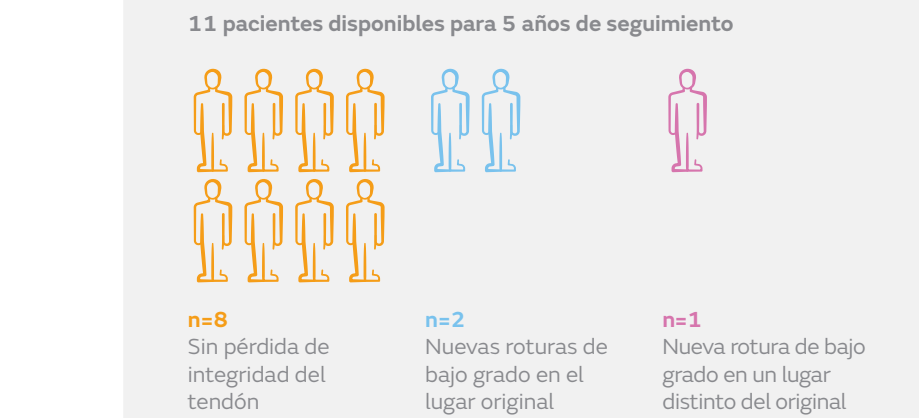


Figura. Cambio en la integridad del tendón (RM) entre los 2 y los 5 años de seguimiento

Disponible en: Muscles, Ligaments and Tendons Journal

2 años

5 años

Mejoras clínicamente significativas en el dolor y la funcionalidad en un estudio multicéntrico de registro del implante bioinductivo REGENETEN◊ en la RMR

McIntyre L, et al. *Arthroscopy* (2019)[7]

Descripción general

- Estudio multicéntrico de registro de 173 pacientes tratados con el implante bioinductivo REGENETEN en lugar de una reparación de PT (n=90) o en combinación con una reparación estándar de roturas de FT (n=83)

Resultados

- En las roturas de PT, las mejoras medias superaron las DMCI en la escala VAS del dolor desde las 2 semanas y la puntuación ASES desde las 6 semanas de postoperatorio (p<0,001)
- En las roturas de FT, las mejoras medias superaron las DMCI en la escala VAS del dolor desde las 2 semanas y la puntuación ASES desde los 3 meses de postoperatorio (p<0,001)
- Las puntuaciones SANE, WORC y VR-12 PCS también mejoraron significativamente desde los valores iniciales durante el período del estudio en ambos tipos de rotura (p<0,001)
- La recuperación postoperatoria fue rápida en las roturas de PT (Tabla)

Conclusiones

El implante bioinductivo REGENETEN produjo mejoras clínicamente relevantes en el dolor y la funcionalidad en pacientes con roturas de PT y FT, con rápida recuperación postoperatoria en las roturas de PT.

Tabla. Duración de la recuperación postoperatoria en pacientes con roturas de espesor parcial

Parámetro	Implante bioinductivo REGENETEN	
Tiempo con cabestrillo	10,6 días Sin cirugía del bíceps	27,7 días Tenodesis concomitante
Volvió a conducir	14,6 días	
Volvió al trabajo	9,4 días Trabajo sedentario	72,9 días Trabajo físico
Volvió a hacer ejercicios de atletismo	65,6 días Generales	117,9 días Ejercicios por encima de la cabeza
Duración del uso de opiáceos	18,3 días	

El anclaje de sutura HEALICOIL◊ REGENESORB◊ se reabsorbió en su mayor parte y fue reemplazado por material óseo nuevo a los 21 meses después de la RMR artroscópica

Vonhoegen J, et al. *J Orthop Surg Res* (2019)[13]

Descripción general

- Estudio retrospectivo evaluando la reabsorción de los anclajes de sutura HEALICOIL REGENESORB en 48 pacientes (82 anclajes) en un seguimiento medio de 21 meses después de la RMR

Resultados

- A los 21 meses, 65/82 anclajes (79 %) no podían distinguirse del material óseo adyacente en una RM (figura)
- Solo se detectó osteólisis en 2/82 anclajes (2,4 %) y ninguna reacción superó el diámetro del anclaje de sutura anterior (5,5 mm); tampoco hubo formación de quistes alrededor del anclaje
- La consolidación completa se logró en 46/48 (96 %) pacientes y no se detectaron complicaciones relacionadas con la resistencia del anclaje

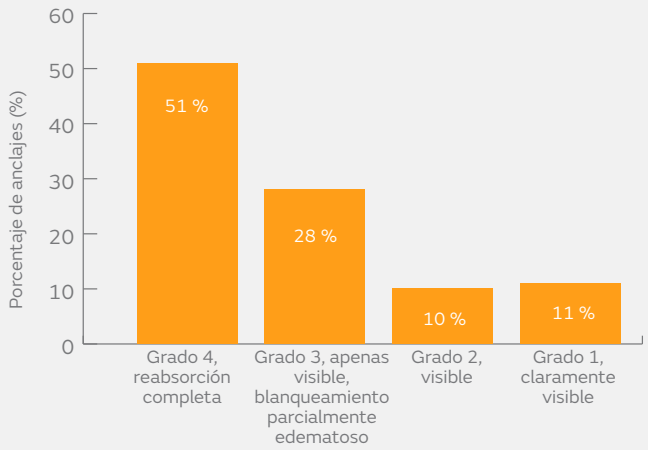


Figura. Reabsorción del anclaje HEALICOIL REGENESORB a los 21 meses después de la operación

Conclusiones

Los anclajes HEALICOIL REGENESORB proporcionan muy buena estabilidad primaria, una degradación fiable y mantiene la calidad ósea de la superficie del manguito de los rotadores.

Resumen del estudio

Comparación con los biocompuestos Arthrex

Disponible en: Journal of Orthopaedic Surgery and Research

Una densidad ósea significativamente mayor rodeando los anclajes de sutura HEALICOIL◊ PK en comparación con los anclajes de sutura TWINFIX◊ PK seis meses después de la RMR

Chahla J, et al. *Arthroscopy* (2020)[9]

Descripción general

- Ensayo controlado aleatorizado en un solo centro comparando los resultados después de una reparación en doble fila de roturas del manguito de los rotadores de espesor completo, con la fila medial fijada con:
  - Anclajes HEALICOIL PK de tipo espiral (n=21)
  - Anclajes TWINFIX PK de tipo tornillo (n=19)

Resultados

- Los anclajes HEALICOIL PK tuvieron una densidad ósea significativamente mayor a los 1,50 mm de distancia y más allá, desde la superficie del anclaje, en comparación con los anclajes TWINFIX PK a los 6 meses (p<0,05; Figura)
- Los anclajes HEALICOIL PK tuvieron una masa ósea total significativamente superior dentro del sitio del anclaje, en comparación con los anclajes TWINFIX PK a los 6 meses (p<0,01); no hubo ninguna diferencia significativa en la densidad
- El dolor y la funcionalidad del hombro mejoraron significativamente comparando el momento inicial y a los 12 meses en ambos grupos (p<0,05)

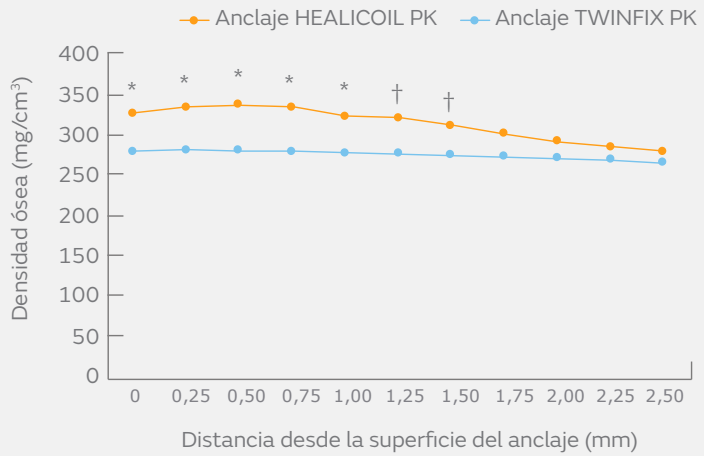


Figura. Densidad ósea a los 2,50 mm de distancia y más allá de la superficie de los anclajes HEALICOIL PK y los anclajes TWINFIX PK en exploraciones de TC a los 6 meses
** p<0,01, †p<0,05*

Conclusiones

Los anclajes HEALICOIL PK de tipo espiral tuvieron una densidad ósea significativamente mayor alrededor del anclaje, en comparación con los anclajes TWINFIX PK de tipo tornillo, 6 meses después de la reparación del manguito de los rotadores. Los autores sugieren que el aumento de la densidad ósea alrededor del anclaje puede contribuir a una estructura más sólida durante la rehabilitación postoperatoria.

El espesor del manguito de los rotadores fue significativamente mayor a las seis semanas en pacientes que recibieron anclajes de sutura fenestrados en comparación a los que recibieron anclajes de sutura no fenestrados

Clark TR, et al. *Am Sport Med Res* (2016)[8]

Descripción general

- Estudio retrospectivo para comparar la consolidación del tendón tras la RMR primaria en pacientes que recibieron, o bien anclajes de sutura fenestrados (anclaje de sutura HEALICOIL◊ REGENESORB◊; n=40) o bien no fenestrados (anclaje Healix Advance™, DePuy Synthes, Raynham, MA, EE. UU.; n=30)

Resultados

- El espesor promedio del manguito de los rotadores, medido por ecografía a las 6 semanas, fue significativamente mayor en los pacientes que recibieron los anclajes HEALICOIL REGENESORB frente a los anclajes Healix Advance. (figura)
- Además del tipo de anclaje, el espesor promedio del manguito de los rotadores también estuvo significativamente relacionado con el sexo (p=0,022), la edad (p<0,001) y el número de días desde la cirugía (p=0,004)

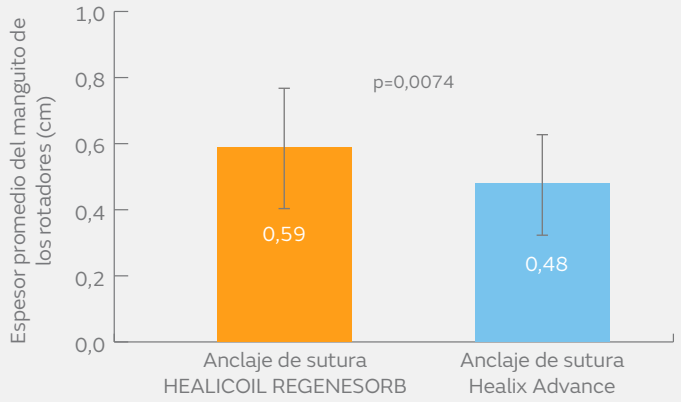


Figura. Espesor promedio (± desviación estándar) del manguito de los rotadores a las 6 semanas

Conclusiones

Los pacientes tratados con anclajes HEALICOIL REGENESORB fenestrados mostraron un espesor del manguito de los rotadores significativamente mayor a las seis semanas que los tratados con anclajes no fenestrados.

Disponible en: Annals of Sports Medicine and Research

Crecimiento de hueso significativamente mejorado con los anclajes de sutura HEALICOIL◊ PK en comparación con los anclajes de sutura TWINFIX◊ HA seis meses después de la RMR

Kim J-H, et al. *Arthroscopy* (2020)[10]

Descripción general

- Ensayo controlado aleatorizado en dos hospitales de Corea del Sur, en el que se comparaba el crecimiento de hueso y los resultados clínicos seis meses después de la RMR con anclajes HEALICOIL PK de diseño abierto (n=36) o anclajes TWINFIX HA no fenestrados (n=33)

Resultados

- Significativamente más anclajes HEALICOIL PK tuvieron un crecimiento óseo bueno o excelente en comparación con los anclajes TWINFIX HA (69,5 frente a 36,3 %; p<0,001; Figura)
- No hubo diferencias importantes entre los grupos del anclaje HEALICOIL PK y el anclaje TWINFIX HA en las tasas de formación de quistes (14 % frente al 12 %) y de nuevas roturas (5 % frente al 5 %)
- Mejoras importantes en la funcionalidad del hombro y el alivio del dolor desde el momento inicial con ambos anclajes (p<0,001); sin diferencias importantes entre grupos

Conclusiones

Los anclajes HEALICOIL PK de diseño abierto tuvieron un crecimiento óseo significativamente mayor en comparación con los anclajes TWINFIX HA no fenestrados, 6 meses después de la reparación del manguito de los rotadores.

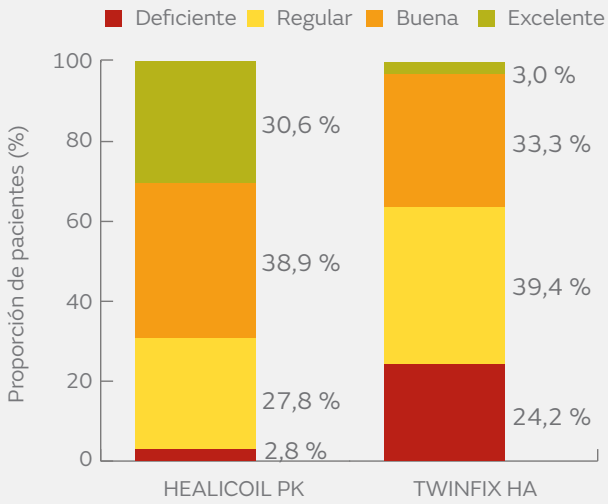


Figura. Crecimiento óseo (escala de osificación de Barber modificada) con anclajes HEALICOIL PK y anclajes TWINFIX HA en las exploraciones de TC a los 6 meses

Las propiedades de fijación, la distribución de la tensión y los patrones de fallo difieren entre los anclajes de sutura de tipo espiral y de tipo tornillo para la RMR

Sano H, et al. *J Orthop Sci* (2016)[11]

Descripción general

- Pruebas de resistencia virtual de los anclajes de sutura de tipo tornillo (anclaje de sutura TWINFIX◊ Ti) y de tipo espiral (anclaje de sutura HEALICOIL◊ PK y anclaje de sutura HEALICOIL REGENESORB◊) utilizando 3D-FEM
- Se insertaron modelos informáticos de cada anclaje en un modelo de hueso esponjoso antes de la simulación de una fuerza de tracción

Resultados

- El lugar de mayor distribución de la tensión y fallo de elementos fue distinto según el tipo de anclaje:
  - Alrededor de las roscas proximales del anclaje TWINFIX Ti de tipo tornillo
  - Cerca de la punta distal y del lugar de fijación del hilo de sutura en los dos anclajes HEALICOIL de tipo espiral
- De los tres anclajes, los anclajes HEALICOIL REGENESORB fueron los que mostraron menor desplazamiento (figura)

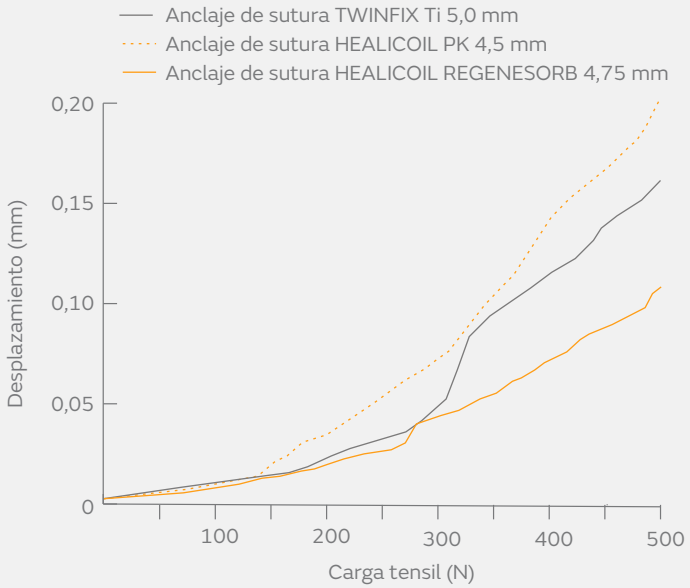


Figura. Valor promedio de desplazamiento para los anclajes de sutura de tipo espiral y de tipo tornillo

Conclusiones

En las pruebas de resistencia virtual, el fallo del anclaje TWINFIX Ti de tipo tornillo ocurrió más cerca de la superficie ósea que con los anclajes HEALICOIL de tipo espiral. Debido a que el tejido óseo proximal se daña con frecuencia durante la reparación, esto puede dar lugar a un mayor riesgo de extracción de los anclajes de tipo tornillo.

Referencias

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Evidence in focus

Study summary

Arnoczky SP, et al. *Arthroscopy* (2017)*

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Supporting healthcare professionals for over 150 years

REGENETEN® Bioinductive Implant is rapidly absorbed and replaced by tendon-like tissue within 6 months

Cell ingrowth by 5 weeks, with progressive maturation to tendon-like tissue

Study overview

- A retrospective study of biopsies taken between 5 weeks and 6 months following arthroscopic rotator cuff repair augmented with the REGENETEN Bioinductive Implant
- Biopsies were collected from 7 patients (6 full-thickness tears and 1 partial-thickness) requiring a second procedure
- Specimens were examined for host-tissue ingrowth, host-tissue maturation and host-implant biocompatibility

Key results

- At the earliest time period (5 weeks), the biopsy showed rapid host cell ingrowth and early collagen formation
- At 3 months, there was increased collagen formation, maturation and organization on the surface of the implant (Figure 1)
- By 6 months, the implant was no longer visible, with new tendon-like tissue and oriented collagen indicative of functional loading (Figure 2)
- No evidence of foreign body or inflammatory reactions at any time point

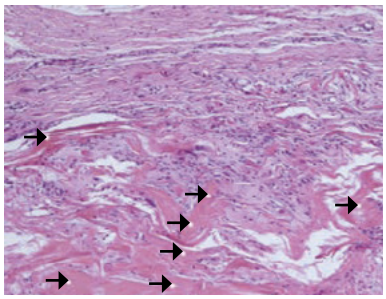

Figure 1. Photomicrograph of surface of implant at 3 months. Remnants of implant still present (→)

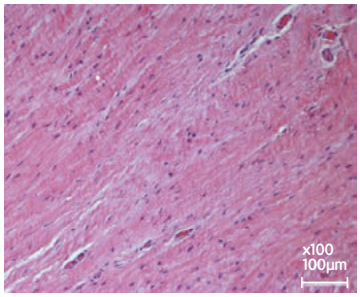

Figure 2. Photomicrograph of surface of implant at 6 months. No evidence of implant remaining

Images included with permission from Dr Craig L. Van Kampen.

Conclusion

The REGENETEN Bioinductive implant is the first to clinically demonstrate regeneration of tendon tissue. Biopsies demonstrated rapid host cell ingrowth and collagen formation, leading to progressive maturation and functional loading of new tissue.

Considerations

- Due to the relatively small sample size and the associated inter-patient variability to healing and graft uptake, the progress of tendon-like tissue has not been directly measured

Study citation

*Arnoczky SP, Bishai SK, Schofield B, et al. Histologic evaluation of biopsy specimens obtained after rotator cuff repair augmented with a highly porous collagen implant. *Arthroscopy* 2017;33(2):278-283.
Available at: Arthroscopy: The Journal of Arthroscopy & Related Surgery

Evidence in focus

Study summary

Bokor DJ, et al. *Muscles, Ligaments, Tendons J* (2015)*

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REGENETEN® Bioinductive Implant maintains repair integrity in full-thickness (FT) rotator cuff tears

Repair integrity supported by rapid induction of new tendon-like tissue which matures and integrates with native tendon

Study overview

- A preliminary analysis of a prospective study of 9 patients (mean age, 56.4 years) with tears of the supraspinatus tendon (8 medium-sized FT tears; 1 high-grade partial-thickness tear converted to a FT tear during surgery)
- All patients received a REGENETEN Bioinductive Implant over the bursal surface of the tendon following standard repair
- MRI and clinical outcome assessments were conducted preoperatively and at 3, 6, 12 and 24 months postoperatively
- Tendon thickness measurements were compared to published values from young healthy adults to determine the relative amount of tissue generation

Key results

- No MRI evidence of re-tear or gap formation, with the integrity of all repaired tendons intact at 24 months
- Significant increase in mean tendon thickness versus published values at 3, 6, 12 and 24 months ($p<0.01$), with an average of 2mm new tissue over the bursal surface (Figure)
- New tissue rapidly matured, improved in quality and was indistinguishable from the native tendon by 12 months
- From 12 to 24 months, tendon thickness slightly decreased, likely reflecting continued functional remodeling
- Significant improvement in clinical scores at 24 months versus preoperative measures
  - Constant-Murley score and Constant-Murley pain score (both $p<0.001$)
  - American Shoulder and Elbow Surgeons (ASES) score and ASES pain score (both $p<0.001$)
- Outcomes were satisfactory for 8/9 patients (89%) at 24 months

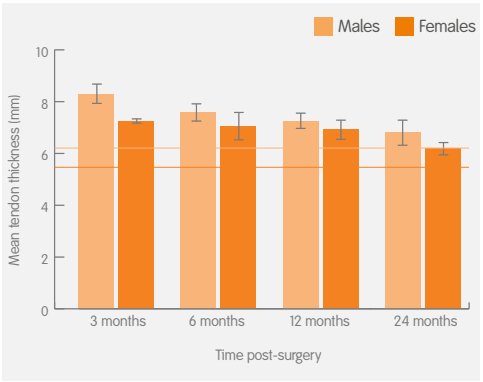

Figure. Mean (± standard error of mean) tendon thickness in male (n=6) and female (n=3) patients compared to published normal average thicknesses (horizontal lines) for healthy males and females; $p<0.01$ at all time points

Conclusion

Through the generation of rapidly maturing new tendon-like tissue, REGENETEN Bioinductive Implant facilitates restoration of the normal tendon footprint and ultimately maintains repair integrity of full-thickness tears over 24 months. These findings are consistent with previous pre-clinical research and a finite element analysis.

Study citation

*Bokor DJ, Sonnabend D, Deady L, et al. Preliminary investigation of a biological augmentation of rotator cuff repairs using a collagen implant: a 2-year MRI follow-up. *Muscles Ligaments Tendons J*. 2015;5(3):144-150.
Available at: Muscle, Ligaments and Tendons Journal

Evidence in focus

Study summary

Schlegel TF, et al. *J Shoulder Elbow Surg* (2017)*

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REGENETEN® Bioinductive Implant induces tendon-like tissue formation in patients with partial-thickness (PT) tears of the supraspinatus (SS) tendon

Significant and clinically meaningful benefits were demonstrated in validated assessments of pain and function

Study overview

- A prospective, multi-center, open-label trial in 33 patients (mean age, 54.6 years) with PT tears of the SS tendon
- All patients received REGENETEN Bioinductive Implant over the bursal surface of the tendon following arthroscopic subacromial decompression without repair
- Tendon thickness and tear size were assessed by MRI preoperatively and at 3 months and 1 year following surgery
- Clinical outcomes were measured using American Shoulder and Elbow Surgeons (ASES) and Constant-Murley assessments, preoperatively and at 3 months and 1 year postoperatively

Key results

MRI outcomes

- At 1 year, 23 patients (70%) had a reduction in tear size of at least one grade from baseline
- Additionally, 8 patients (24%) had no visible defect at 1 year
- Tear progression only occurred in one patient, who did not follow the rehabilitation protocol
- No patients underwent revision surgery
- Significant increase in mean tendon thickness in both intermediate and high grade tears at 1 year ($p<0.01$; Figure 1)
- No significant differences in tendon thickness between:
  - Intermediate and high-grade tears
  - Articular surface and bursal-sided defects

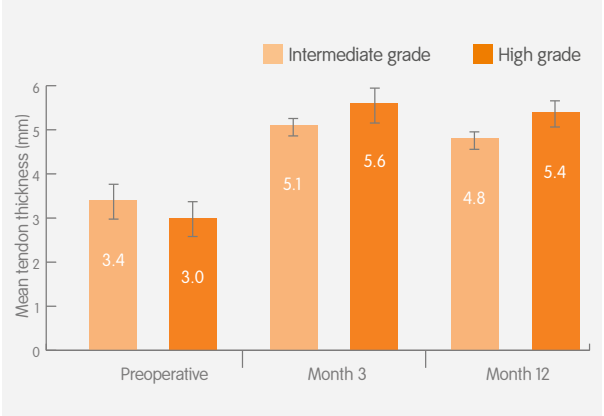

Figure 1. Mean change in tendon thickness (± standard error) across intermediate and high grade tears. At month 12, $p=0.003$ and $p<0.0001$ for intermediate and high-grade tears respectively, versus preoperative measures

Continued P2 >>

Evidence in focus (continued)

Key results (continued)

Patient outcomes

- Significant improvements in ASES shoulder index, pain and shoulder function scores at 1 year (all p<0.0001)
  - Improvements in ASES pain and ASES shoulder index scores were approximately twice the minimal clinically important differences (MCIDs; Figures 2 and 3)
- Significant improvement in Constant-Murley shoulder score from 57.1 at baseline to 81.4 at 1 year (p<0.0001), greater than twice the MCID of 10.4
- At 1 year, 30 patients (94%) agreed or strongly agreed that they were satisfied with the results of their procedure
- Recovery was considered rapid by the investigators when compared with patients undergoing tear conversion and repair:
  - Mean sling time: 23.3±2.4 days
  - Mean return to work: 30.5±12.0 days
  - Mean duration of physical therapy: 18±1.6 visits

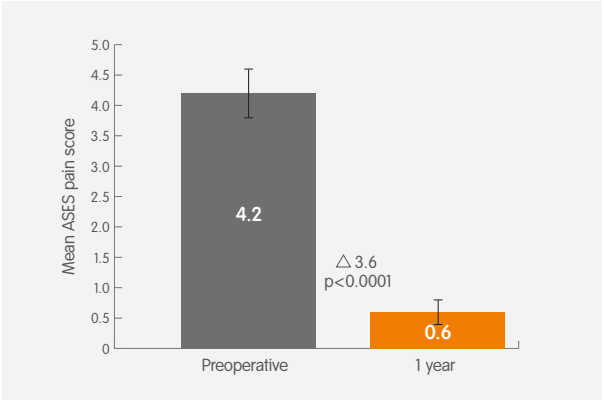

Figure 2. Mean ASES pain score before and after treatment with the REGENETEN Bioinductive Implant; MCID: 1.4

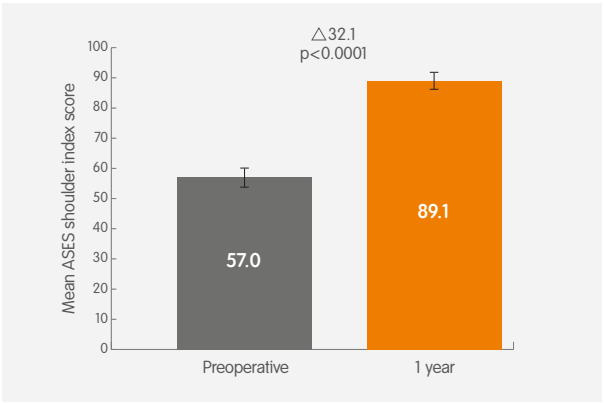

Figure 3. Mean ASES shoulder index score before and after treatment with the REGENETEN Bioinductive Implant; MCID: 12.01-16.92

Conclusion

The REGENETEN Bioinductive Implant biologically augments healing, increasing tendon thickness and creating an environment conducive to healing. Therefore, REGENETEN Bioinductive Implant represents a promising treatment for patients with intermediate and high-grade PT tears of the SS tendon.

Study citation

*Schlegel TF, Abrams JS, Bushnell BD, Logan Brock J, Ho CP. Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial thickness tears: a prospective multicenter study. *J Shoulder Elbow Surg* 2017;27(2):242-251.
Available at: Journal of Shoulder and Elbow Surgery

Evidence in focus

Study summary

Thon SG, et al. *Am J Sports Med* (2019)*

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REGENETEN® Bioinductive Implant leads to tissue induction and high rates of tendon healing in patients with large and massive rotator cuff tears

Consistent treatment success in primary repairs and revisions with no implant-related adverse events

Study overview

- A prospective study of 23 patients (mean age, 57.9 years) with large (two tendon, n=11) and massive (three tendon, n=12) rotator cuff tears receiving primary (n=7) or revision (n=16) repairs
- Following a double-row repair, a REGENETEN Bioinductive Implant was applied over the repaired supraspinatus and infraspinatus tendons
- Primary outcome was safety. Secondary outcomes included tendon thickness as an assessment of tissue induction on each ultrasound (US) examination (3, 6, 12 and 24 months) and on a single MRI (mean follow-up, 13 months), and American Shoulder and Elbow Surgeons (ASES) score at 24 months
- Standard postoperative rehabilitation protocol for large/massive rotator cuff tears was followed

Key results

- No implant-related adverse events were reported
- Complete tendon healing in 22/23 patients (96%) on both imaging modalities (US and MRI)
- Treatment success in 21/23 patients (91%) at 24 months; 1 healing failure and 1 clinical failure due to progression of glenohumeral osteoarthritis
- Mean tendon thickness increased from 6.29mm at 3 months to 7.72mm at 12 months, decreasing to 7.28mm at 24 months
- Mean ASES score was 82.87 at 24 months
- No significant difference in treatment success (Figure), tendon thickness or ASES score between primary and revision repair groups or between large and massive tear groups

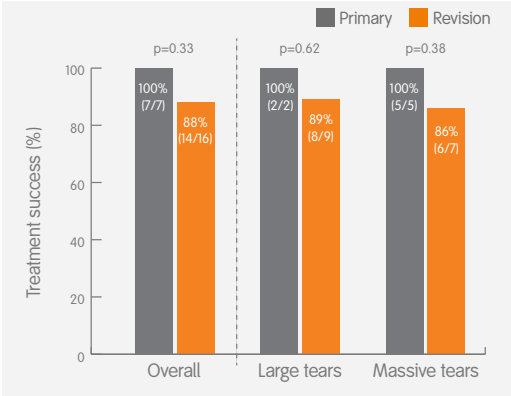

Figure. Percentage of patients achieving treatment success in primary and revision repairs

Conclusion

Tendon healing is often unsuccessful following repair of large and massive rotator cuff tears, especially in the revision setting. In conjunction with repair of large and massive tears, REGENETEN Bioinductive Implant was safe, induced tissue formation and resulted in a relatively high tendon healing rate in both primary and revision settings. These findings are consistent with the healing response seen in partial-thickness tears.

Considerations

- Tendon thickness was measured at the lateral edge of the articular cartilage and slightly posterior to the bicipital groove; the authors suggested a usual thickness in normal rotator cuffs of 8mm with this measurement technique

Study citation

Thon SG, O'Malley L, O'Brien MJ, Savoie FH. Evaluation of healing rates and safety with a bioinductive collagen patch for large and massive rotator cuff tears: 2-year safety and clinical outcomes. *Am J Sports Med*. 2019;47(8):1901-1908.

Evidence in focus

Study summary

Bokor DJ, et al. *Muscles, Ligaments, Tendons J* (2016)*

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REGENETEN® Bioinductive Implant promotes rapid and sustained healing of partial-thickness (PT) rotator cuff tears

Tear healing is linked to significant improvement in function and reduction in pain compared to preoperative values over 24 months

Study overview

- A prospective study of 13 patients (mean age, 53.8 years) with various grades and locations of PT tears of the supraspinatus tendon
- All patients received a REGENETEN Bioinductive Implant over the bursal surface of the tendon following arthroscopic subacromial decompression without repair
- MRI and clinical outcome assessments were conducted preoperatively and at 3, 6, 12 and 24 months postoperatively

Key results

- Significant mean increase in tendon thickness of 2.2mm at 3 months versus preoperative values ($p<0.0001$)
- At 12 months, new tissue was indistinguishable from underlying tissue in 12/13 patients (92%)
- Tendon thickness at 24 months was significantly thicker ($p<0.0001$) than preoperative values
- At 12 months, all assessable patients had a reduction in tear size of ≥1 grade, with complete tear disappearance in 7 of 10 patients with measurable tear size (70%) (Figure)
- Significant improvement in clinical scores throughout 24-month follow-up period
  - Constant-Murley score ($p\leq0.01$) and Constant-Murley pain score ($p\leq0.001$)
  - American Shoulder and Elbow Surgeons (ASES) total score and ASES pain score (both $p\leq0.001$)
- Outcomes were satisfactory for 12/13 patients (92%) at 24 months, suggesting a benefit over acromioplasty alone

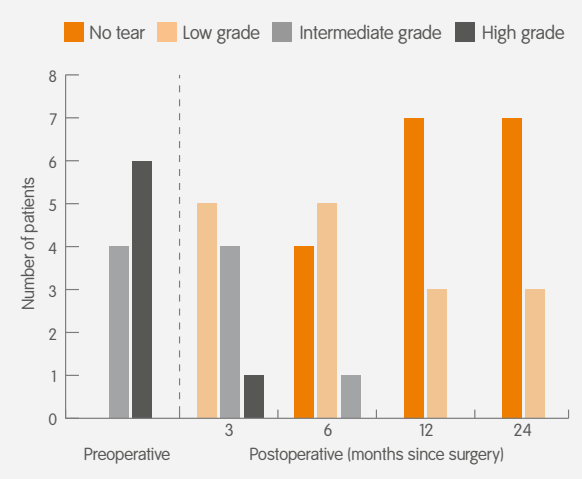

Figure. Sequential improvement and healing of cuff defects over 24 months (n=10)

Conclusion

When treated with REGENETEN Bioinductive Implant, partial-thickness rotator cuff tears can decrease in size and in most cases completely heal. Tear healing is associated with the formation of load-bearing, tendon-like tissue, ultimately leading to improved clinical outcomes.

Study citation

*Bokor DJ, Sonnabend D, Deady L, et al. Evidence of healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a collagen implant: a 2-year MRI follow-up. *Muscles Ligaments Tendons J*. 2016;6(1):16-25.

Available at: Muscle, Ligaments and Tendons Journal

✚ Evidence in focus

Publication summary: Bokor DJ, et al. *MLTJ*. (2019)*

Smith+Nephew

Improved tendon thickness and integrity was sustained five years after treatment with the REGENETEN◊ Bioinductive Implant

✚ Plus points

Comparison of 5-year findings with 2-year follow-up:

73%
Most patients had no decline in tendon integrity

Significant improvements
in pain and function sustained to 5 years

No additional
complications

Overview

- Five-year follow-up of a prospective, single-arm study evaluating REGENETEN Bioinductive Implant in lieu of repair in patients with partial-thickness rotator cuff tears
- 11/13 enrolled patients (mean age, 54.0 years) were available for assessment
- Outcomes were assessed 5 years postoperatively and were compared to findings at 2 years (previously reported):
  - MRI assessment of tendon integrity and thickness
  - Patient-reported outcomes (American Shoulder and Elbow Surgeons [ASES] shoulder scale and Constant-Murley shoulder score)

Results

- 8/11 patients (73%) had no decline in tendon integrity between 2 and 5 years (Figure)
- Tendon thickness significantly decreased between 2 and 5 years (5.9 vs 5.2mm; p=0.0012), but remained significantly greater than preoperative values (4.2mm; p<0.0001; Figure)
- Significant improvements from baseline in pain and function were sustained to 5 years (p≤0.01) and were not significantly different to 2-year values
- No additional complications between 2 and 5 years

Figure. Change in tendon integrity (MRI) between 2- and 5-year follow-up

Conclusions

REGENETEN Bioinductive Implant demonstrated sustained effectiveness in improving tendon thickness and integrity, with no reduction in patient-reported outcomes between 2 and 5 years.

Citation

*Bokor DJ, Sonnabend DH, Deady L, et al. Healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a highly-porous collagen implant: a 5-year clinical and MRI follow-up. *MLTJ*. 2019;9(3):338-347.
Available at: Muscles, Ligaments and Tendons Journal

Evidence in focus

Publication summary

McIntyre L, et al. *Arthroscopy* (2019)*

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Supporting healthcare professionals for over 150 years

Clinically meaningful improvements in pain and function at one year in a multicentre registry study of REGENETEN® Bioinductive Implant for the treatment of partial- and full-thickness rotator cuff tears

Time to return to driving and sport compared favourably to published results from patients treated with standard surgical techniques

Study overview

- A multicentre registry study of 173 patients who received a REGENETEN Bioinductive Implant in lieu of partial-thickness repair (n=90) or in conjunction with standard repair of full-thickness tears (n=83)
- Patients available at follow-up had a mean age of 54.2 years, were 57% male and included diabetics (10.4%), smokers (14.4%), patients involved in a worker's compensation claim (12.1%) and chronic opioid users (7.5%)
- Outcomes included postoperative recovery and patient-reported outcome measures of pain and function (ASES, SANE, VAS pain, VR-12 and WORC scores) at baseline and at regular intervals to 1 year of study follow-up

Key results

Partial-thickness tears

- MCIDs were achieved in VAS pain from 2 weeks (5.3 at baseline to 3.3 at 2 weeks and 1.1 at 1 year; p<0.001) and ASES score from 6 weeks (47.0 at baseline to 60.6 at 6 weeks and 85.6 at 1 year; p<0.001)
  - Mean VAS pain and ASES score at 3 months were significantly improved compared to published results from patients undergoing transtendon or takedown repair without a REGENETEN Bioinductive Implant (p<0.05)
- Significant improvements from 6 weeks in SANE score (42.5 at baseline to 59.4 at 6 weeks and 86.0 at 1 year; p<0.001), VR-12 PCS (35.8 at baseline to 39.1 at 6 weeks and 49.7 at 1 year; p<0.002) and WORC index (38.2 at baseline to 53.5 at 6 weeks and 84.4 at 1 year; p<0.001)
- Time in sling and time to return to driving and sport was rapid compared to published results for standard surgical techniques (Table 1)

Measure	REGENETEN Bioinductive Implant	
Time in sling	10.6 days No biceps surgery	27.7 days Concomitant tenodesis
Return to driving	14.6 days	
Return to work	9.4 days Sedentary work	72.9 days Physical work
Return to athletics	65.6 days Overall	117.9 days Overhead athletics
Duration of opioid use	18.3 days	

Table 1. Duration of postoperative recovery in patients with partial-thickness tears

Key results (continued)

Full-thickness tears

- MCIDs were achieved in VAS pain from 2 weeks (5.2 at baseline to 3.7 at 2 weeks and 1.2 at 1 year; p<0.001) and ASES score from 3 months (45.5 at baseline to 68.4 at 3 months and 83.8 at 1 year; p<0.001)
- Significant improvements from 6 weeks in WORC index (35.0 at baseline to 41.1 at 6 weeks and 80.1 at 1 year; p<0.001), and from 3 months in SANE score (39.2 at baseline to 63.3 at 3 months and 80.7 at 1 year; p<0.001) and VR-12 PCS (34.5 at baseline to 40.8 at 3 months and 45.7 at 1 year; p<0.001)
- Time to return to driving and sport was rapid compared to published results for standard surgical techniques (Table 2)

Measure	REGENETEN® Bioinductive Implant	
Time in sling	34.0 days No biceps surgery	39.4 days Concomitant tenodesis
Return to driving	24.5 days	
Return to work	21.8 days Sedentary work	62.5 days Physical work
Return to athletics	119.2 days Overall	143.7 days Overhead athletics
Duration of opioid use	26.9 days	

Table 2. Duration of postoperative recovery in patients with full-thickness tears

Complications

- Complications requiring revision surgery were failure of cuff healing (n=4), postoperative infection (n=1), deep vein thrombosis and adhesive capsulitis (n=1), postoperative stiffness (n=1) and recurrent effusions (n=1)

Conclusion

REGENETEN Bioinductive Implant led to clinically meaningful improvements in pain and function for patients with partial- and full-thickness tears. Return to driving and sport compared favourably to standard surgical techniques, suggesting that REGENETEN Bioinductive Implant may also enhance postoperative recovery.

Considerations

- Only comparisons to MCIDs for ASES score and VAS pain were made by the authors. However, the improvements from preoperative values in SANE score, VR-12 PCS and WORC index also exceeded the MCIDs reported in existing literature for rotator cuff repair[1-3]

Study citation

*McIntyre LF, Bishai SK, Brown PB, Bushnell BD, Trenhaile SW. Patient-reported outcomes following use of a bioabsorbable collagen implant to treat partial and full-thickness rotator cuff tears. *Arthroscopy.* 2019 July 23. [Epub ahead of print]
Available at: Arthroscopy

References
1. Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the shoulder. *Arthroscopy.* 2003; 19(10):1109-1120. 2. Cvetanovich GL, Gowd AK, Liu JN, et al. Establishing clinically significant outcome after arthroscopic rotator cuff repair. *J Shoulder Elbow Surg.* 2019; 28:939-948. 3. Zhou L, Natarajan M, Miller BS, Gagnier JJ. Establishing minimal important differences for the VR-12 and SANE scores in patients following treatment of rotator cuff tears. *Orthop J Sports Med.* 2018;6(7):2325967118782159.

Abbreviations
ASES = American Shoulder and Elbow Surgeons, MCID = minimal clinically important difference, NR = not reported, SANE = Single Assessment Numeric Evaluation, VAS = visual analogue scale, VR-12 = Veterans RAND 12-item Health Survey, VR-12 PCS = Veterans RAND 12-item Health Survey Physical Component Score, WORC = Western Ontario Rotator Cuff

Evidence in focus

Study summary

Vonhoegen J, et al. *J Orthop Surg Res* (2019)*

smith&nephew

Supporting healthcare professionals for over 150 years

HEALICOIL◇ REGENESORB biocomposite suture anchor mostly resorbed and replaced by new bone material within 21 months of arthroscopic rotator cuff repair (RCR)

No severe osteolysis or cyst formation observed at any anchor site

Study overview

- Retrospective, single-centre study assessing the resorption and osteoconductive properties of a novel biocomposite material REGENESORB, comprising 65% polylactic-co-glycolic acid (PLGA), 15% beta-tricalcium phosphate (ß-TCP) and 20% calcium sulfate (CS)
  - 48 patients underwent arthroscopic single-row RCR with 5.5mm HEALICOIL REGENESORB Suture Anchor (82 suture anchors, average 1.71 anchors per patient)
- Outcomes included MRI evaluation of implant resorption, osteolysis and re-tear rate at a mean follow-up of 21.2 months

Key results

- At 21 months, 79% of implants (75% patients) could not be distinguished from adjacent bone material (Figure)
  - No significant correlation between anchor resorption and age, re-tear rate, defect size, gender, number of anchors, and grade of retraction
- Osteolysis was detected in only 2/82 anchors (2.4%), with no reaction exceeding the diameter of the former suture anchor (5.5mm) and no peri-anchor cyst formation
  - No significant correlation between osteolysis and patient age, gender, re-tear rate, or size of the defect
- Complete healing was achieved in 46/48 (96%) patients and no anchor pull-out complications were detected

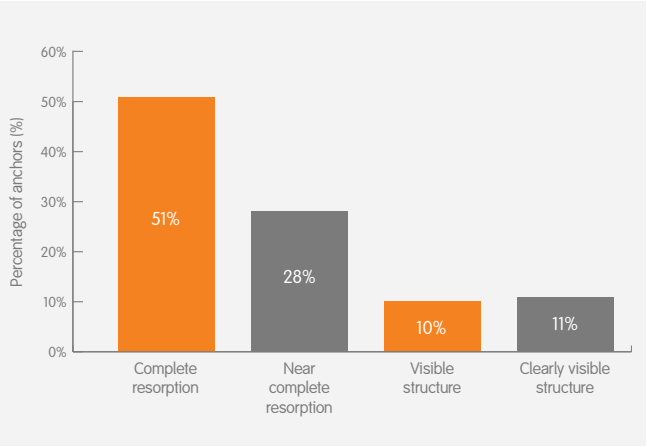

Figure. Level of resorption of 82 implanted suture anchors

Conclusion

HEALICOIL REGENESORB biocomposite suture anchor provides strong primary stability, reliable degradation and maintains bone quality of the rotator cuff footprint. Preserving bone quality aids the clinical situation when revision surgery is required. Resorption characteristics and osteolysis occurrence appeared superior compared to existing evidence of commonly used anchor materials containing PLLA (poly-L-lactide) and PDLDA (poly-D-L-lactide).

Study citation

*Vonhoegen J, John D, Hägermann C. Osteoconductive resorption characteristics of a novel biocomposite suture anchor material in rotator cuff repair. *J Orthop Surg Res.* 2019;14(1):12.
Available at: Journal of Orthopaedic Surgery and Research

✚ Evidence in focus

Smith+Nephew

Focus on biocomposite suture anchor resorption

Introduction

Biocomposite suture anchors composed of biodegradable polymers and osteoconductive materials are commonly used in rotator cuff repair.[1] Osteoconductive materials were introduced in response to the poor bone replacement and bone-derived complications associated with polymer-only anchors.[1-5] However, despite their widespread use, the resorption process of biocomposite suture anchors for rotator cuff repair has only recently been studied.[1,2]

HEALICOIL◊ REGENESORB◊ Suture Anchors[1]

Overview

Retrospective study evaluating resorption of 18.5mm HEALICOIL REGENESORB Suture Anchors in 48 patients (82 anchors).

Anchor resorption was evaluated by MRI 21 months after rotator cuff repair.

Anchor material composition		
65%	**15%**	**20%**
PLGA	β-TCP	Calcium sulphate

Results

- Resorption at 21 months (Figure 1):
  - Complete or near complete resorption of 65/82 suture anchors (79%)
  - Only 17/82 suture anchors (21%) were visible or clearly visible
- No severe osteolysis

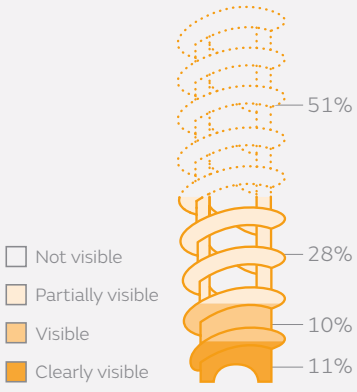

Figure 1. Resorption of HEALICOIL REGENESORB Suture Anchors

Arthrex BioComposite™ Suture Anchors[2]

Overview

Retrospective study evaluating resorption of 14.7mm Biocomposite Corkscrew® and 19.1mm Biocomposite SwiveLock® anchors (Arthrex, Naples, FL, USA) in 25 patients (84 anchors).

Anchor resorption was evaluated by MRI 28 months after rotator cuff repair.

Anchor material composition	
85%	**15%**
PLLA	β-TCP

Results

- Resorption at 28 months (Figure 2):
  - Complete or near complete resorption of only 28/84 suture anchors (33%)
  - Two-thirds of suture anchors (56/84, 67%) remained visible or clearly visible
- No severe osteolysis

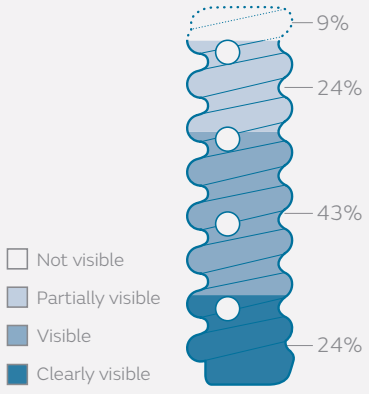

Figure 2. Resorption of Arthrex BioComposite suture anchors

Commentary

- The material composition and physical structure of biocomposite suture anchors affects their resorption[1,2]
- In separate clinical studies, resorption of more than twice as many HEALICOIL REGENESORB Suture Anchors was complete or near complete at 21 months compared to 85% PLLA and 15% β-TCP suture anchors at 28 months[1,2]
- Successful anchor resorption and bone replacement offers benefits for patients requiring revision surgery[1,2]

Abbreviations
β-TCP = β-tricalcium phosphate, MRI = magnetic resonance imaging, PLGA = poly-L-lactic co-glycolic acid, PLLA = poly L-lactic acid

References
1. Vonhoegen J, John D, Hägermann C. *J Orthop Surg Res*. 2019;14(1):12. **2**. Sgroi M, Friesz T, Schocke M, Reichel H, Kappe T. *Clin Orthop Relat Res*. 2019;477(6):1469-1478. **3.** Dhawan A, Ghodadra N, Karas V, et al. *Am J Sports Med*. 2012;40(6):1424-1430. **4**. Duralde XA. *Clin Orthop Relat Res*. 2019;477:1479-1482. **5**. Milewski MD, Diduch DR, Hart JM, et al. *Am J Sports Med*. 2012;40(6):1392-1401.

✚ Evidence in focus

Publication summary: Chahla J, et al. *Arthroscopy* (2020)*

Smith+Nephew

Significantly greater bone density surrounding coil-type HEALICOIL◊ PK Suture Anchors versus screw-type TWINFIX◊ PK Suture Anchors 6 months after rotator cuff repair

✚ Plus points

Significantly greater bone density at and around the surface of HEALICOIL PK anchors versus TWINFIX PK anchors ($p<0.05$)

Significantly more total bone mass within the anchor sites of HEALICOIL PK anchors versus TWINFIX PK anchors ($p<0.01$)

Overview

- Single-centre randomised controlled trial comparing outcomes after double-row repair of full-thickness rotator cuff tears, with the medial row fixated with either:
  - Coil-type HEALICOIL PK anchors (n=21)
  - Screw-type TWINFIX PK anchors (n=19)
- Outcomes included:
  - Bone density at and around the anchor site at 6 months
  - Composition of synovial fluid-bone marrow aspirate collected from the anchor site during surgery
  - Pain and shoulder function at 6 and 12 months

Results

- HEALICOIL PK anchors had significantly greater bone density at and up to 1.50mm from the anchor surface compared to TWINFIX PK anchors ($p<0.05$; Figure)
- HEALICOIL PK anchors had significantly more total bone mass within the anchor site compared to TWINFIX PK anchors ($p<0.01$); there was no significant difference in density
- Pain and shoulder function improved significantly from baseline to 12 months in both groups ($p<0.05$)
- Growth factors and stem cells detected in synovial fluid-bone marrow aspirate during surgery were similar in both groups

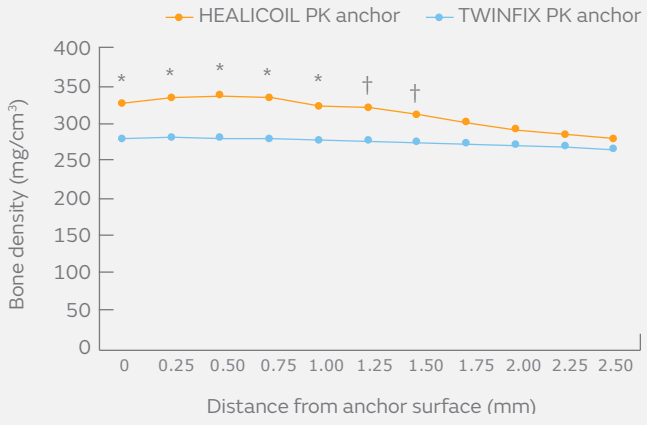

Figure. Bone density at and up to 2.50mm away from the surface of HEALICOIL PK anchors and TWINFIX PK anchors
** p<0.01, † p<0.05*

Conclusions

Coil-type HEALICOIL PK anchors had significantly greater bone density surrounding the anchor compared to screw-type TWINFIX PK anchors 6 months after rotator cuff repair. The authors suggested that increased bone density around the anchor may contribute to a stronger construct during postoperative rehabilitation.

Citation

*Chahla J, Liu JN, Manderle B, et al. Bony ingrowth of coil-type open-architecture anchors compared with screw-type PEEK anchors for the medial row in rotator cuff repair: a randomized controlled trial. *Arthroscopy*. 2020;36(4):952-961.
Available at: Arthroscopy

Evidence in focus

Study summary

Clark TR, et al. *Am Sport Med Res* (2016)*

smith&nephew

Supporting healthcare professionals for over 150 years

Mean rotator cuff thickness significantly greater in patients who received vented compared with non-vented suture anchors at 6 weeks

Vented suture anchors for rotator cuff repair may provide greater healing potential at 6 weeks postoperatively

Study overview

- Retrospective study comparing tendon healing following primary rotator cuff repair in patients who received either vented suture anchors (HEALICOIL® REGENESORB suture anchor; n=40) or non-vented suture anchors (Healix Advance™ suture anchor, DePuy Synthes, Raynham, MA, USA; n=30)
- Patients in the vented group were younger than those in the non-vented group (mean age: 55.0±10.1 years vs 62.5±10.7 years, respectively), but there was no difference between groups in terms of days post-op, handedness or gender
- To assess healing, rotator cuff thickness was measured at the medial anchor site by ultrasound at 6 week follow-up
- Both patients and physicians conducting the ultrasound were blinded to the type of anchor used

Key results

- Mean rotator cuff thickness was significantly greater in patients who received HEALICOIL REGENESORB suture anchor vs Healix Advance suture anchor (0.59cm vs 0.48cm; p=0.0074; Figure)
- Mean rotator cuff thickness was significantly greater in:
  - Males vs females, 0.59±0.17cm and 0.49±0.17cm, respectively (p=0.022)
  - Younger vs older patients (p<0.001)
  - Patients with more days post-op vs those with fewer (p=0.004)

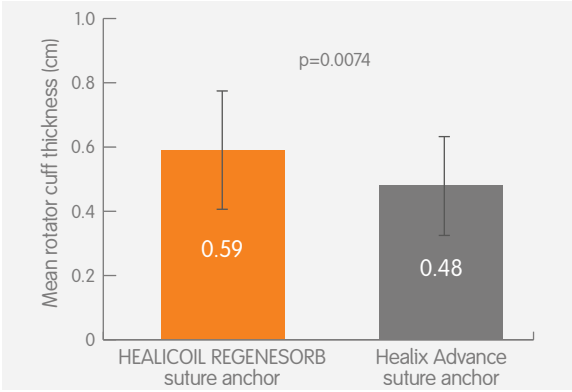

Figure. Mean (± standard deviation) rotator cuff thickness at 6 weeks

Conclusion

This is the first study comparing tendon healing following rotator cuff repair with vented and non-vented suture anchors. Patients treated with vented suture anchors had a significant increase in rotator cuff thickness at six weeks versus those treated with non-vented anchors. These findings support the theory that vented suture anchors provide a biologic healing advantage.

Considerations

- Two surgeons operated on all patients. Most patients in the non-vented group received surgery from a single surgeon, whereas the vented group had a smaller ratio between operating surgeons
- Results were only collected at 6-week follow-up, other studies have denoted rotator cuff and muscle healing can take up to six months to see full effect

Study citation

*Clark TR, Guerrero EM, Song A, O'Brien MJ and Savoie FH. Do vented suture anchors make a difference in rotator cuff healing. *Am Sport Med Res.* 2016;3(3):1068.
Available at: Annals of Sports Medicine and Research

✚ Evidence in focus

Publication summary: Kim J-H, et al. *Arthroscopy* (2020)*

Smith+Nephew

Significantly improved bone ingrowth with HEALICOIL◊ PK Suture Anchors versus TWINFIX◊ HA Suture Anchors 6 months after rotator cuff repair

✚ Plus points

Significantly more HEALICOIL PK anchors had good or excellent bone ingrowth compared to TWINFIX HA anchors (p<0.001)

No significant difference in cyst formation between HEALICOIL PK anchor and TWINFIX HA anchor groups (14 vs 12%)

Overview

- Randomised controlled trial in two South Korean hospitals comparing bone ingrowth and clinical outcomes after rotator cuff repair with open-architecture HEALICOIL PK anchors (n=36) or non-vented TWINFIX HA anchors (n=33) for medial row fixation
- Postoperative outcomes included:
  - CT evaluation of bone ingrowth and cyst formation at 6 months
  - MRI or ultrasound evaluation of re-tear at 12 months
  - Shoulder function and pain at 3, 6 and 12 months, and final follow-up (mean, 25.2 months)

Results

- Significantly more HEALICOIL PK anchors had good or excellent bone ingrowth compared to TWINFIX HA anchors (69.5 vs 36.3%; p<0.001; Figure)
  - Excellent bone ingrowth was observed in 11 patients (30.6%) treated with HEALICOIL PK anchors compared to only 1 patient (3.0%) treated with TWINFIX HA anchors
- No significant difference in cyst formation between HEALICOIL PK anchor and TWINFIX HA anchor groups (14 vs 12%)
- No significant difference in re-tear rate between HEALICOIL PK anchor and TWINFIX HA anchor groups (5 vs 5%)
- Significant improvements in shoulder function and pain relief from baseline with both anchors (p<0.001); no significant differences between groups

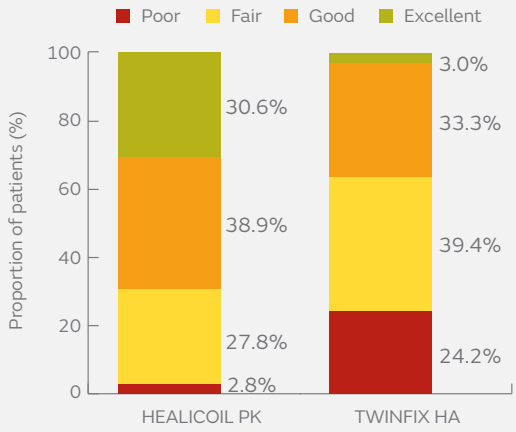

Figure. Bone ingrowth (Modified Barber's ossification scale) with HEALICOIL PK anchors and TWINFIX HA anchors at 6 months

Conclusions

Open-architecture HEALICOIL PK Suture Anchors had significantly improved bone ingrowth compared to non-vented TWINFIX HA Suture Anchors 6 months after rotator cuff repair. Rates of cyst formation were similar and the authors suggested that the open-architecture of HEALICOL PK anchors may allow early and sufficient bone ingrowth before cyst formation occurs.

Citation

* Kim J-H, Kim Y-S, Park I, et al. A comparison of open-construct PEEK suture anchor and non-vented biocomposite suture anchor in arthroscopic rotator cuff repair: a prospective randomized clinical trial. *Arthroscopy*. 2020;36(2):389-396.
Available at: Arthroscopy

Evidence in focus

Study summary

Sano H, et al. *J Orthop Sci* (2016)*

smith&nephew

Supporting healthcare professionals for over 150 years

Fixation properties, stress distribution and failure patterns differ between coil-type and screw-type suture anchors for rotator cuff repair

HEALICOIL◇ REGENESORB suture anchor had the best initial fixation properties of anchors tested

Study overview

- An independent study conducting virtual pull-out testing using 3-dimensional finite element method (3D-FEM)
- Computer models of three anchors; one screw-type anchor (TWINFIX◇ Ti suture anchor), and two coil-type anchors (HEALICOIL PK suture anchor and HEALICOIL REGENESORB suture anchor) were inserted into the isotropic cube model that simulated cancellous bone
- A tensile load (500 N) along the long axis of the inserted anchor was applied to the site of suture thread attachment to simulate a traction force

Key results

- With TWINFIX Ti screw-type suture anchor, the highest stress and element failure occurred around the anchor threads, closest to the surface of the cube
- Conversely, the highest stress and element failure with both coil-type anchors occurred deeper, near the anchor tip and site of suture thread attachment
- HEALICOIL REGENESORB suture anchor showed the least displacement of any anchor tested, with less than 0.1mm displacement at a load of 500N, vs 0.1mm displacement at 400N and 370N for TWINFIX Ti suture anchor and HEALICOIL PK suture anchor, respectively (Figure)

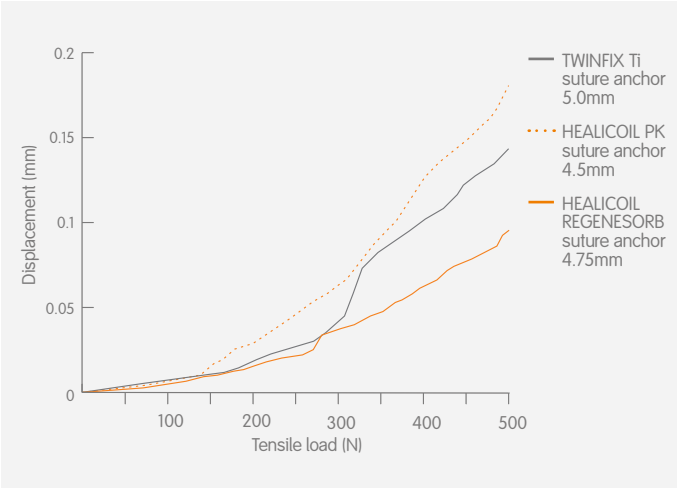

Figure. Mean value of displacement

Conclusion

In virtual pullout testing of the screw-type anchor, stress distribution and element failure occurred around the proximal threads, whereas in coil-type anchors, stress and element failure occurred nearer the distal anchor tip. As proximal bony tissue is often damaged during repair, this may lead to a greater risk of pull-out with screw-type anchors. HEALICOIL REGENESORB suture anchor had the best initial fixation properties of all anchors tested.

Considerations

- 3D-FEM is a computer aided engineering tool, which has been validated in the prediction of femoral and vertebrae fractures and has been used to predict the failure risk of inserted implants

Study citation

*Sano H, Tokunaga M, Noguchi M, et al. Comparison of fixation properties between coil-type and screw-type anchors for rotator cuff repair: A virtual pullout testing using 3-dimensional finite element method. *J Orthop Sci.* 2016;21(4):452-457.