

+ Rotator cuff repair

An evidence based look at Advanced Healing Solutions

Smith+Nephew



+ Age is the dominant risk factor for rotator cuff re-tear¹

- Re-tear rates have been shown to double in the 50-59 age bracket compared to those below 50²
- Bone mineral density, which is known to decrease with age, also correlates with re-tear rate³

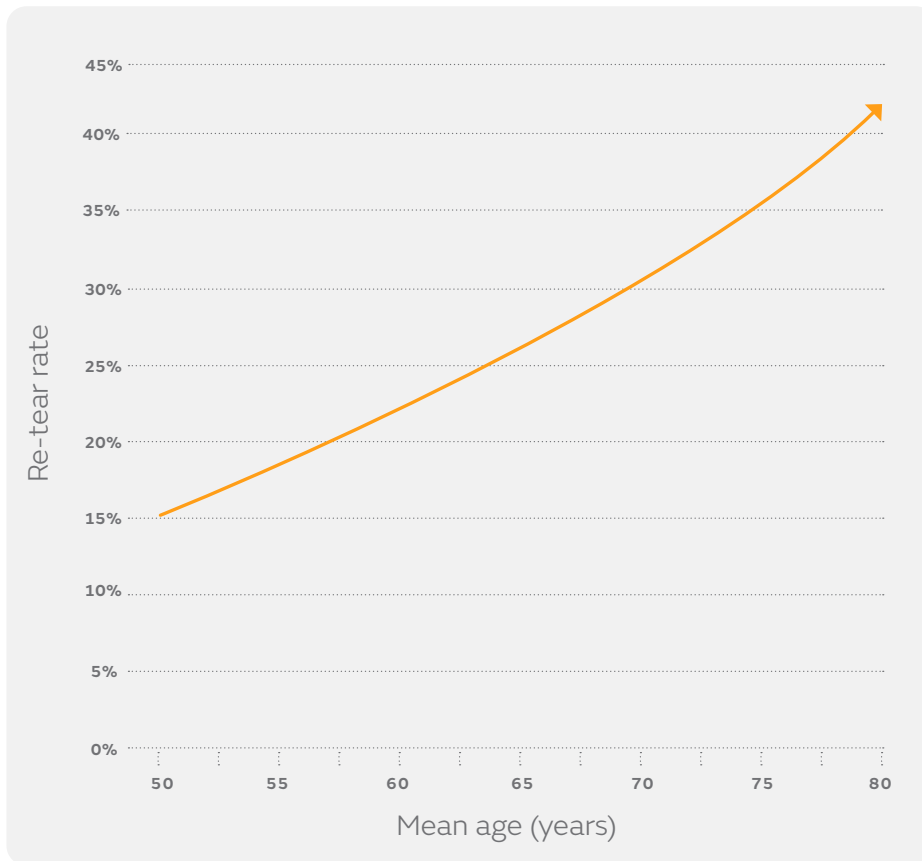


Figure: Graph of age vs. re-tear rate. The risk of re-tear doubled from 15% at age 50 years to >30% at age 70 years.⁴

2x
re-tear rates
for ages 50-59,
compared to <50²



Bone mineral
density decreases
with age³



+ Patients who undergo revision rotator cuff surgery can be twice as likely to have a re-tear compared to those undergoing primary repair*⁵

- A meta-analysis has shown patients with re-tear have significantly poorer function than those without re-tear ($p < 0.001$)⁶
- Following a revision surgery, patients experience increased pain, weaker strength and motion and have lower satisfaction with shoulder function compared to those undergoing primary repair surgery⁵

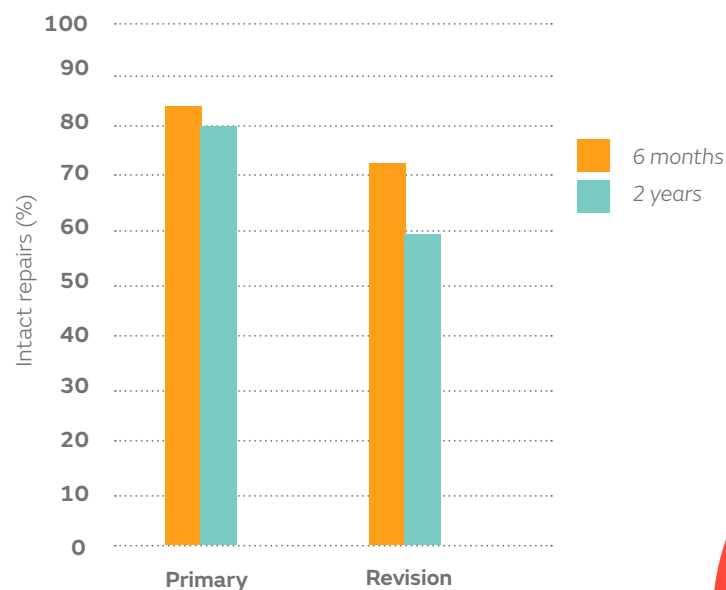


Figure: Intact repairs (%) for primary and revision surgery at 6 months and 2 years⁵

*n=310, primary; n=50, revision



✚ Repair constructs can specifically address osteopenic bone^{7,8} associated with patients over 50³

- Open architecture anchors have been shown to increase bone density surrounding the anchor⁹ and potentially improve healing potential¹⁰

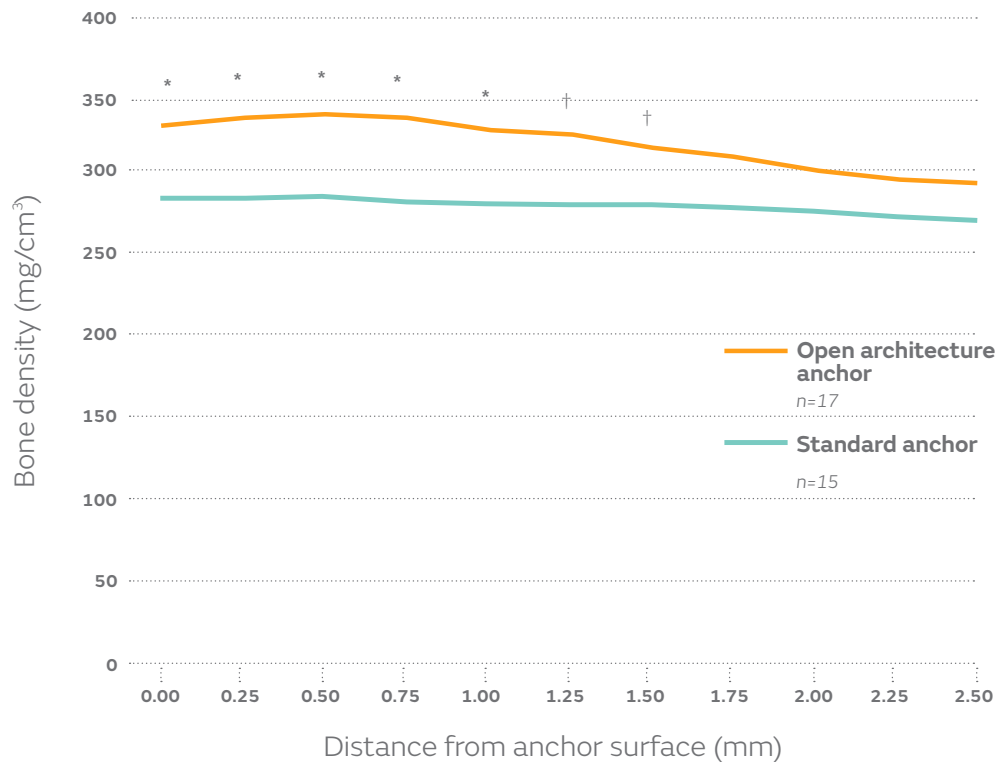


Figure: Bone density at, and up to 2.50mm away from, the surface of an open architecture anchor and a standard anchor on 6-month CT scans. *= $p < 0.01$, †= $p < 0.05$.

- In a model of osteoporotic bone, open architecture anchors had a significantly greater failure load compared to standard anchors⁷ ($p < 0.05$)
- Knotless anchors with an internal suture locking mechanism perform consistently and may be advantageous in osteopenic bone⁸

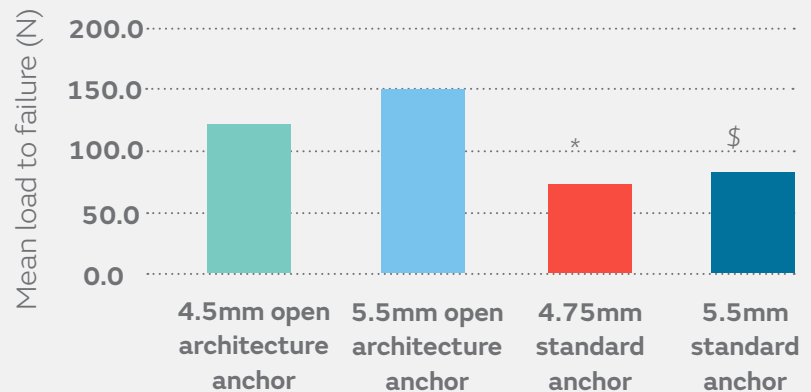


Figure: Mean load to failure (N) of PEEK open architecture and standard anchors in 5-pcf Sawbone. Statistical significance ($p < 0.05$) vs * 4.5mm and \$ 5.5mm open architecture anchors⁷

+ Advanced healing solutions

The HEALICOIL[®] Family of suture anchors is redefining healing potential for rotator cuff repair

- The HEALICOIL anchor family features an open architecture design which allows bone to interdigitate within the thread profile
- Superior bone growth has been demonstrated at 6 months compared to solid anchors; this may contribute to higher pullout strength and offer the potential for reduced failure⁹
- Treatment of patients with a HEALICOIL Suture Anchor resulted in a greater rotator cuff thickness at 6 weeks post op compared to those treated with a non-vented anchor¹⁰
- The HEALICOIL KNOTLESS anchor features an internal locking mechanism, the suture is securely locked in place providing an additional point of fixation^{*11}

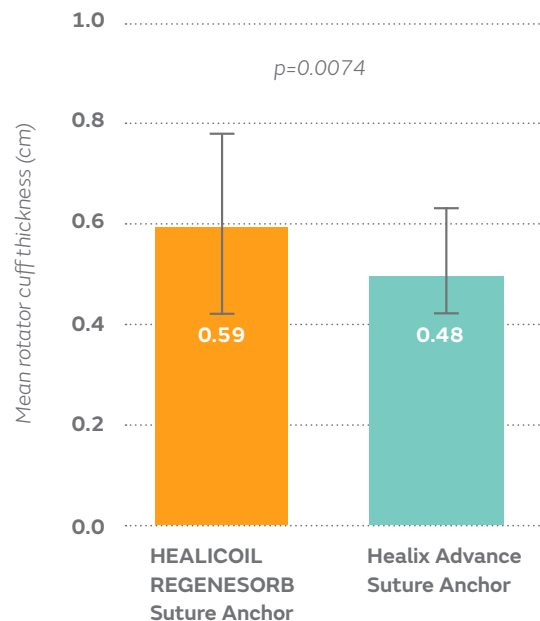
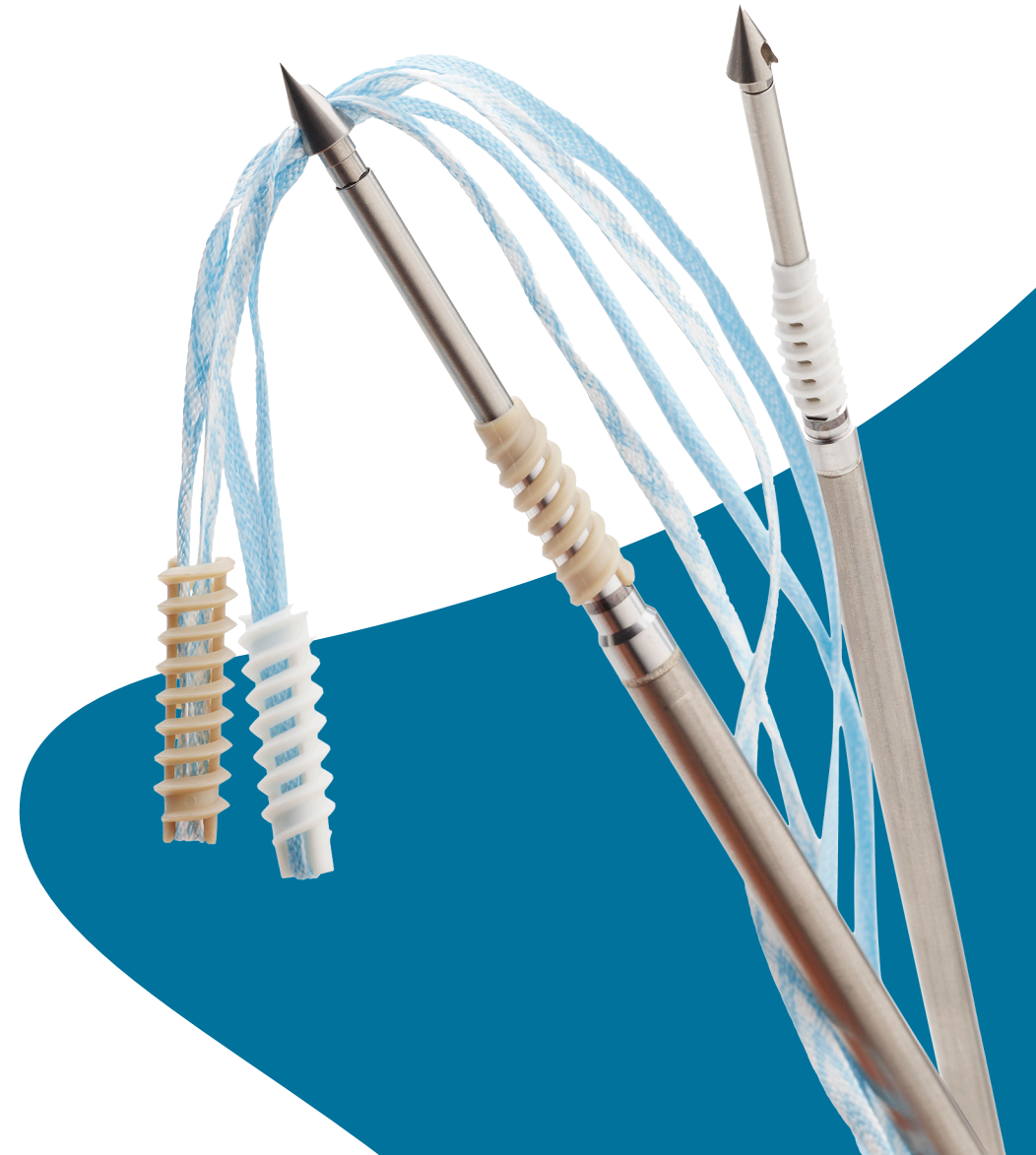


Figure: Mean (\pm standard deviation) rotator cuff thickness at 6 weeks¹⁰

*As demonstrated in benchtop testing



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

References

1. Rashid MS, Cooper C, Cook J et al. Increasing age and tear size reduce rotator cuff repair healing rate at 1 year. Data from a large randomized controlled trial. *Acta Orthopaedica*. 2017; 88(6):606-611. **2.** Diebold G, Lam P, Walton J et al. Relationship between age and re-tear rate. A study of 1600 consecutive rotator cuff repairs. *J Bone Joint Surg*. 2017;99:1198-205. **3.** Kwon J, Hoon Kim S, Hyn Lee Y et al. The Rotator Cuff Healing Index: A New Scoring System to Predict Rotator Cuff Healing After Surgical Repair. *Am J Sports Med*. 2019;47(1):173-180. **4.** Khazzam M, Sager B, Box H et al. The effect of age on risk of re-tear after rotator cuff repair: a systematic review and meta analysis. *J Shoulder Elb Surg*. 2020;4:625-631. **5.** Shamsudin A, Lam P, Peters K et al. Revision versus primary surgery arthroscopic rotator cuff repair: a 2 year analysis of outcomes in 360 patients. *Am J Sports Med*. 2014;43(3). **6.** Yang J, Robbins M, Reilly J et al. The clinical effect of a rotator cuff re-tear: a meta-analysis of arthroscopic single row and double row repairs. *Am J Sports Med*. 2017;45(3):733-41. **7.** Yamauchi S, Tsukada H, Sasaki E et al. Biomechanical analysis of bioabsorbable suture anchors for rotator cuff repair using osteoporotic and normal bone models. *J Orthop Sci*, 2021. **8.** Woodmass JM, Mathewson G, Ono Y et al. Suture locking of isolated internal locking knotless suture anchors is not affected by bone quality. *Open Access J Sports Med*. 2015;6:201-208. **9.** 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. **10.** Clark TR, Guerrero EM, Song A, O'Brien MJ and Savoie FH. Do vented suture anchors make a difference in rotator cuff healing. *Ann Sport Med Res*. 2016;3(3):1068. **11.** Data on file at Smith+Nephew, internal report no. 15009718, 2020