

## Original Article

# Rotator Cuff Repair with Graft Augmentation Improves Function, Decreases Revisions, and Is Cost-Effective

Ryan Quigley, M.D., Ph.D., Nikhil Verma, M.D., Aghogho Evarherhe Jr., B.S., and Brian J. Cole, M.D., M.B.A.

**Purpose:** The purpose of this study is to evaluate the cost effectiveness of the use of extracellular matrix (ECM) augment at the time of primary rotator cuff repair utilizing a decision tree analysis. **Methods:** A decision tree model was created utilizing the existing literature for retear rates with and without dermal graft augmentation. Costs for rotator cuff repair (hospital and surgeon fees) were based on published studies and the cost for graft augmentation was based on institutional data. Utility measures were based upon EQ-5D (European Quality of Life 5 Dimension) scores to assess for improvement in quality adjusted life years (QALY) over a 10-year postoperative period with and without graft augmentation. Cost effectiveness was assessed using the incremental cost effectiveness ratio (ICER), or the incremental cost for per QALY with graft augmentation. Cost effectiveness is based on previous literature whereby an intervention is considered cost effective if the ICER is less than \$50,000/QALY. **Results:** On the basis of our decision tree analysis, total cost for rotator cuff tear without augmentation was \$12,763, while the cost increased to \$16,039 with ECM augmentation. With graft augmentation there was an improvement in 2.29 QALY, while there was an improvement of 2.05 without graft augmentation. The ICER of graft augmentation is \$14,000/QALY, well below the cost effectiveness cut-off of \$50,000/QALY. Sensitivity analysis showed the maximum cost of the ECM augment to be cost effective is \$11,921. **Conclusion:** Graft augmentation does come with a significant upfront cost; however, on the basis of our decision-tree analysis, it may represent a cost-effective procedure. There is evidence to potentially consider more routine use in rotator cuff repairs, while being cost effective. **Level of Evidence:** Economic: Level IV: computer simulation model (Monte Carlo simulation, Markov model) with inputs derived from Level IV studies.

## Introduction

Rotator cuff injuries remain the most common cause of shoulder pain in adults and are largely degenerative or attritional in nature.<sup>1</sup> The annual incidence of rotator cuff repair continues to rise.<sup>2,3</sup> This increase comes at significant economic cost with at least 250,000 rotator cuff repairs being performed annually in the United States as of 2012 and likely more than 500,000 per year as of 2021,<sup>2</sup> accounting for at least \$5 billion per year in medical costs, benefits, and lost productivity.<sup>4,5</sup> Despite the increasing incidence of

repairs and health care resources used for their surgical intervention, retear rates remain high.<sup>6</sup> A review by McElvany concluded that rotator cuff repair outcomes have not appreciably improved in the last 30 years.<sup>7</sup> It is clear there is a pressing need to improve outcomes following rotator cuff surgery, specifically as it relates to rotator cuff healing.<sup>8</sup> This need also occurs at a time when our health care system places a premium on value-based care and optimized patient outcomes with a concomitant reduction for the need for revision surgery.

*From the Kaiser Permanente, Sacramento, California, U.S.A. (R.Q.); and Midwest Orthopaedics at Rush, Department of Orthopaedic Surgery, Rush University Medical Center, Chicago, Illinois, U.S.A. (N.V., A.E., B.J.C.).*

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*Address correspondence to Brian J. Cole, M.D., M.B.A., 1611 W. Harrison St., Chicago, IL 60612, U.S.A. E-mail: [brian.cole@rushortho.com](mailto:brian.cole@rushortho.com)*

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Retears following rotator cuff repair remain very high, with current literature show re-tear rates of 10-90%.<sup>6</sup> One systematic review looking at 9 randomized controlled trials of operative vs non operative management of rotator cuff tears even went so far to claim that it remains uncertain if surgery provides meaningful benefits to patients with symptomatic tears.<sup>9</sup> A meta-analysis by McElvany<sup>7</sup> of over 8000 rotator cuff repairs showed that, little progress has been made in improving clinical outcomes, healing rates and recovery timelines. Retears have been associated with patient age,<sup>10</sup> preoperative fatty atrophy,<sup>11</sup> and tear size.<sup>7</sup> Despite these re-tear rates, some studies report no difference in patient outcome measures regardless of repair integrity.<sup>12</sup> However, more contemporary critical analysis of patient satisfaction and function following repair demonstrates that anatomic integrity does play an important role in achieving an optimal functional outcome following surgical intervention and reduces the need for revision surgery<sup>13-15</sup> and strength recovery.<sup>16</sup>

Supplementation of rotator cuff repairs with an extracellular matrix (ECM) graft was developed as a means to augment initial construct mechanical strength, and to provide an improved biologic environment to enhance the reparative process. Dermal allografts are currently the most commonly utilized grafts selected as an adjunct to rotator cuff repair given their superior biomechanical properties, biologic composition including human collagen, and long term incorporation into surrounding host tissues.<sup>17</sup> Biomechanical studies have shown significantly higher load to failure and less displacement with cyclic loading compared to non-augmented repairs.<sup>18-20</sup> Animal studies have also shown that these grafts are bio-conductive leading to graft incorporation with histologic appearance of native tendon.<sup>21-23</sup>

The basic science foundation and support for the use of ECM augmentation has led to significant clinical interest. A prospective blinded study by Gilot et al.<sup>24</sup> comparing standard repairs versus those augmented with an ECM graft in large and massive tears demonstrated that the ECM augmentation group had a lower re-tear rate compared to the control group (10% vs 26%, respectively), improved PROMs (patient reported outcome measures) including: visual analog scale, American Shoulder and Elbow Surgeons score, Short Form 12, and Ontario Rotator Cuff index. Another randomized controlled trial of 69 patients with 24 month follow-up reported that acellular dermal allograft augmentation led to a healing rate of 97.6% of patients compared to 59.5% in the control group.<sup>25</sup> Additionally, postoperative MRI showed improved tendon thickness and footprint coverage in the ECM augmentation group. Lastly, a recent meta-analysis of the literature by Bailey et al.<sup>26</sup> of 5 studies involving

397 shoulders showed that ECM graft augmentation leads to lower re-tear rates, and improved ASES scores compared to conventional repair alone.

Given the recent literature suggesting improved healing rates and patient outcomes with graft augmentation, the purpose of this study is to evaluate the cost effectiveness of the use of extracellular matrix (ECM) augment at the time of primary rotator cuff repair using a decision tree analysis. Our hypothesis is that graft augmentation is cost effective, while leading to improved patient outcomes.

## Methods

### Model Design

We used a decision tree based analytic model to determine the cost effectiveness of graft augmentation in rotator cuff repair. The use of cost effective analyses in health care decision making has been utilized since the 1960s and is recognized by healthcare payers to be a valid tool to assess health care decisions.<sup>27</sup> A decision tree model was built using Amua software platform (Fig 1) in which a simulated cohort of patients undergo rotator cuff repair either with or without an ECM augment at the time of rotator cuff repair. Post-operatively, patients could have a healed repair, or a re-tear. For those with a healed repair, this was considered a terminal outcome for our analysis. Among those in the re-tear group they were again stratified as asymptomatic, or symptomatic. For those with an asymptomatic re-tear, this was again considered a terminal outcome for our analysis. Within those with a symptomatic re-tear they were further stratified as those that eventually underwent a revision or those that did not, each considered terminal outcomes in our analysis.

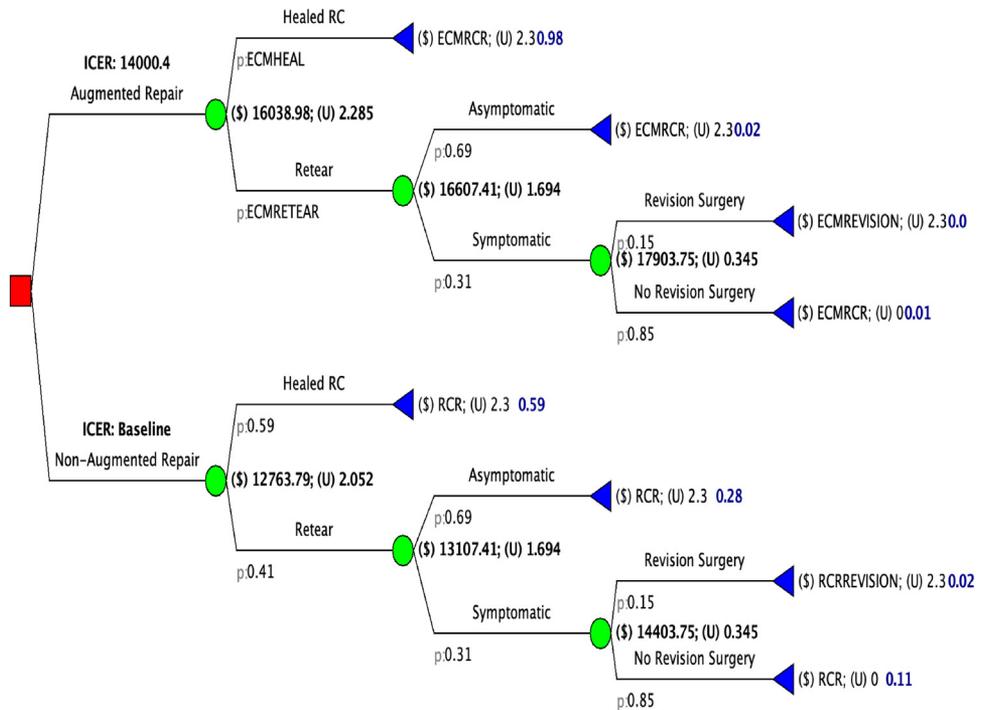
In order to complete our decision tree analysis, certain assumptions were made: (1) individuals could only undergo a single revision procedure, (2) patients with a healed rotator cuff tear did not seek further treatment, (3) patients with an asymptomatic re-tear did not seek further treatment, (4) patients undergoing a revision rotator cuff repair were assumed to heal the repair and gain the same utility as a primary repair that healed, and (5) patients with a symptomatic re-tear that elected not to undergo revision surgery were assumed to get no utility from the intervention. These assumptions led to a simplified clinical scenario, but these assumptions were necessary for economic analysis.

### Model Parameters

#### Costs

Each terminal limb of the decision tree (healed repairs, asymptomatic re-tears, and symptomatic re-tears) is associated with a total cost of care and the total improvement in quality adjusted life years (QALY) over a 10-year period for our trial. The costs for each

**Fig 1.** Decision tree model for evaluation of cost effectiveness of rotator cuff augmentation. ECM-REVISION, cost of primary repair with extracellular matrix (ECM) augment plus additional revision surgery (\$28,550). ECMRCR, cost for repair with ECM augment (\$16,025). RCR, cost for repair without augment (\$12,525). RCRREVISION, cost of primary repair without augment plus additional revision surgery (\$25,050).



treatment arm can be seen in Table 1. The cost for a rotator cuff repair was based on previous studies in the literature and valued at \$12,525 (including hospital and surgeon fees).<sup>4,28,29</sup> The cost of ECM augmentation was based on institutional cost data of \$3,500, which includes the graft and kit for graft fixation (including anchors). The cost for revision rotator cuff repair was conservatively assumed to be the same as the primary nonaugmented repair.

**Utilities**

The derived utility for each terminal outcome can be seen in Table 1. Utility measurements were based upon EQ-5D (European Quality of Life 5 Dimension) scores

from the literature for patients with a torn rotator cuff, and after successful repair.<sup>30-32</sup> These were converted to improvement in QALY over a 10-year period. For the purpose of our analysis, it was assumed that a healed rotator cuff tear in each group did equally well whether it was healed with or without a graft. Conservatively, it was also assumed that an asymptomatic retear would have the same utility as a healed rotator cuff, as has been done in other studies.<sup>33</sup> A symptomatic retear was assumed to have no improvement in utility.

**Transition Probabilities**

In each treatment arm, there are three possible terminal outcomes: healed repairs, asymptomatic retears,

**Table 1.** Transition Probability, Utility, and Cost Inputs for Decision Tree Model

Transition Probabilities		Level of Evidence	Source/Reference
ECM retear rate	.024	I	34
Nonaugmented retear rate	.41	I	34
Asymptomatic retear	.69	IV	35
Symptomatic retear	.31	IV	35
Symptomatic shoulder undergoing revision	.15	II	28
<b>Utility</b>			
Rotator cuff tear	.58 (Range .54-.66)	IV	4,31,32
Healed rotator cuff	.81 (Range .74-.86)	IV	4,31,32
Asymptomatic retear	.81		
Symptomatic retear	.58		
<b>Costs</b>			
Rotator cuff repair (hospital/surgeon fees and therapy)	\$12,525	N/A	4,28,29
ECM cost	\$3,500 (graft and kit)	N/A	Institutional Data
Rotator cuff revision (hospital/surgeon fees and therapy)	\$12,525	N/A	4,28,29

and symptomatic retears. In the decision tree, each subsequent arm has a transition probability that has been pooled from the literature<sup>28,34,35</sup> (Table 1). The estimate for re-tear after repair for both groups was based on the only randomized control trial comparing augmented and nonaugmented rotator cuff repairs in terms of re-tear rates.<sup>34</sup> Avanzi et al. showed a re-tear rate of 2.4% with graft augmentation versus 41% in the nonaugmented repair group at a 2-year follow up in a study of small-to-medium tears. The rate of symptomatic versus asymptomatic retears was based on Plachel et al., which found that 69% of their retears were asymptomatic.<sup>35</sup> There is little data in the literature regarding the percentage of symptomatic retears that ultimately undergo revision surgery, so a conservative value of 15% was used, as has been used in other cost effectiveness analysis studies.<sup>28</sup>

### Analysis

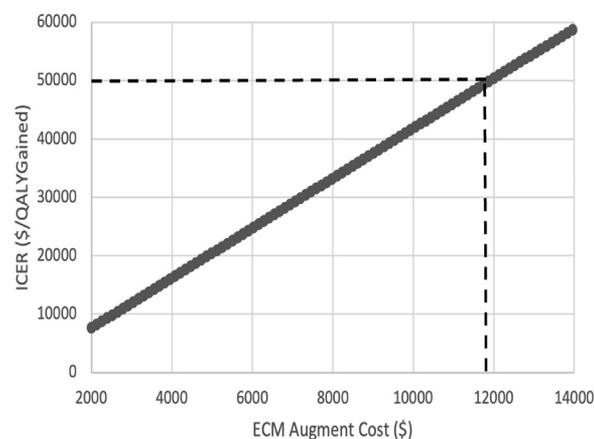
The incremental cost effectiveness ratio (ICER) was determined by first measuring the increased cost with utilization of an ECM augment compared to the control group (no augment). The difference in improvement of QALY was then calculated between the ECM augment and the control (no augment). The incremental cost effectiveness ratio (ICER) was determined by measuring the increased cost with utilization of an ECM augment compared to the control group (no augment) and dividing by the increase in QALY between groups. A value of \$50,000/QALY was utilized to be considered cost effective, as is widely accepted in the literature.<sup>30,32</sup>

### Sensitivity Analysis

Sensitivity analysis was performed in a twofold fashion. First, a one-way sensitivity analysis was performed modifying the cost of the ECM augment while holding all other variables constant and reanalyzing the ICER. This was used to determine the maximum cost of the ECM graft for it to remain cost effective with an ICER < \$50,000. Second, a threshold sensitivity analysis was performed to determine for various ECM augment costs, how much the absolute re-tear rate would have to decrease compared to the control non-augmented repair (41% in our analysis) in order to remain cost effective with an ICER of <\$50,000. This was done by varying the re-tear rate in the ECM augment treatment arm across multiple ECM augment costs and determining the maximum ECM augment re-tear rate to maintain and ICER of < \$50,000. Our decision tree model and sensitivity analysis were all performed with the assistance of an expert statistician.

### Results

The results for our decision tree can be seen in Fig 1. The use of ECM augmentation resulted in an increase in QALY from 2.052 in the nonaugment group to 2.285



**Fig 2.** One-way sensitivity analysis comparing ECM augment costs with calculated ICER. The dashed lines represent the threshold ICER of \$50,000/QALY in order to be cost effective and our calculated maximum cost of the ECM augment, \$11,921 that remains cost effective.

in the augment group. The use of ECM augmentation also result in higher costs: \$16,039 with ECM compared to \$12,763 without augmentation. When evaluating for ICER, the incremental cost for use of ECM augmentation per QALY gained was \$14,000/QALY, well below the \$50,000/QALY considered as a cutoff for cost-effectiveness. This analysis shows that the use of ECM augmentation can be both cost-effective and lead to improved patient outcomes.

Sensitivity analysis was performed using a one-way sensitivity analysis and threshold sensitivity analysis. In our one-way sensitivity analysis, the cost of the ECM augment was varied and ICER was calculated for each cost (Fig 2). This analysis showed that the total ECM augment cost could be as much as \$11,921 and still remain under the ICER threshold of \$50,000/QALY. Our threshold sensitivity analysis was used to determine, at various ECM augment costs, how much the re-tear rate would have to be decreased compared to our control rate (41% in nonaugmented repairs) in order to achieve cost-effectiveness (Table 2). At the current cost of \$3,500, the absolute re-tear rate would have only to decrease 11.4% with an ECM augment compared to nonaugmented repair re-tear rate in order to be cost effective.

### Discussion

Our study has shown that augmentation of primary rotator cuff repairs with ECM augments is highly cost effective with an ICER of \$14,000 based on our institutional cost of \$3,500 for the graft and kit. Our analysis shows that augmented rotator cuff repairs lead to greater improvement in QALY compared to non-augmented repairs (2.28 QALY over a 10-year period compared to 2.05 QALY). Additionally, our sensitivity analysis shows that an augment could cost up to

**Table 2.** Threshold Sensitivity Analysis Showing for Various ECM Graft Costs the Reduction in Retear Rate Compared to a Nonaugmented Needed to Achieve Cost-Effectiveness (ICER < \$50,000/QALY)

ECM Augment Cost	Absolute Reduction in Retear Rate Needed Compared to Nonaugmented Repair (41%)
\$1,000	3.3%
\$2,000	6.5%
\$3,000	9.7%
\$3,500	11.4%
\$4,000	13.0%
\$5,000	16.2%
\$6,000	19.5%
\$7,000	22.6%
\$8,000	25.6%
\$9,000	29.1%
\$10,000	32.4%

\$11,921 and still remain cost effective. This remains considerably above our institutional cost for an ECM augment, and other readily available grafts on the market. Our threshold sensitivity analysis also showed that our current cost, only a small absolute reduction in retears with use of ECM augmentation (11.4%) is required in order to remain cost effective. This is well below the difference of 38.6% seen in the randomized control trial by Avanzi et al., in which the re-tear rate was 41% in the nonaugmented group, and 2.4% in the augmented repair group.<sup>34</sup>

The economic burden of rotator cuff repairs is significant and is estimated conservatively at \$5 billion, including direct and indirect costs (e.g., time lost and worker's compensation), with a large majority of this related to preliminary care and aftercare from the surgery.<sup>5,30</sup> The direct costs (hospital and surgeon fees) of a rotator cuff repair in the United States are estimated at \$7,500-\$13,000 for a primary repair. It has been estimated that the direct costs of a revision rotator cuff repair ranges between \$7,500 and \$13,600.<sup>28-30,36</sup> These revision rotator cuff repair costs do not take into account the extensive additional direct costs associated with subsequent clinic visits, physical therapy, and advanced imaging prior to any revision surgery. In addition, in patients who require revision surgery, the total treatment time may exceed 1 year, which is a significant financial and social burden for the patient. Revision rotator cuff repair due to retears and poor patient outcomes remain a significant economic burden

to the healthcare system and is increasing in incidence.<sup>37</sup>

Many studies have shown that age-related changes within the tendon lead to decreased tendon vascularity, collagen fiber organization, and even collagen composition.<sup>38-45</sup> Although rotator cuff tears have largely been viewed as a mechanical failure, abundant evidence exists that supports chronic and progressive biologic changes that are present prior to an actual tear occurring. This is particularly evident when considering the age-related incidence of rotator cuff tears<sup>29,46-49</sup> (Table 3). When contemplating why early structural failure occurs despite sound biomechanical repair constructs employed in contemporary repair techniques, the biologic hurdle of patient-specific factors, inherent physiologic degeneration, and loss of vascularity in rotator cuff disease provides a likely explanation.<sup>50</sup>

For a rotator cuff repair to heal, there must first be sufficient initial mechanical strength in the repair to resist either suture-tendon failure or tendon-bone failure during the early phases of the healing. Second, there must be sufficient biologic healing potential within the tendon and bone for healing to occur. In a multicenter prospective study with 113 patients, Iannotti et al. found that 94.7% of their retears occurred within the first 6 months,<sup>50</sup> highlighting that the initial healing at the tendon-bone interface is the "weak link" in the majority of retears. However, despite optimization of the mechanical construct for rotator cuff repair,<sup>51,52</sup> biologic limitations present the remaining hurdle to improving patient outcomes, decreasing recovery burden, and providing a more normal histologic tendon-bone interface.

Multiple materials have been considered for graft augmentation, including allograft dermis, fascia lata, xenograft dermis, pericardium, intestinal mucosa, and synthetic nonabsorbable graft materials. Dermal allografts are currently the most commonly used grafts selected as an adjunct to rotator cuff repair given their superior biomechanical properties, biologic composition, including human collagen, and long-term incorporation into surrounding host tissues.<sup>17</sup> In comparison to intestinal mucosal patches, which are completely resorbed, acellular dermal allograft patches incorporate with host tenocytes as initially demonstrated in a sheep model.<sup>53</sup> Basic science studies have also shown that human tenocytes have the highest proliferation and

**Table 3.** Rotator Cuff Tear Incidence by Decade of Life

Study	Sample Size	Imaging Method	Age <50	Age 50-59	Age 60-69	Age 70-79	Age 80-89
Tempelhof et al., 1999 <sup>46</sup>	411	U/S	N/A	13%	20%	31%	51%
Moosmayer et al., 2009 <sup>29</sup>	420	U/S	N/A	2.1%	5.7%	15%	N/A
Jeong et al., 2017 <sup>47</sup>	486	U/S	0%	3.5%	13.3%	11.1%	N/A
Minagawa et al., 2013 <sup>48</sup>	664	U/S	0%	10.7%	15.2%	26.5%	36.6%
Yamamoto et al., 2010 <sup>49</sup>	1366	U/S	0.05%	12.8%	25.6%	45.8%	50%

cellular activity when grown on dermally based structures.<sup>54</sup> Additionally, human dermal allograft had the highest load-to-failure of all tested commercially available grafts.<sup>17</sup>

Biomechanical studies have demonstrated a significant benefit of graft augmentation on initial fixation strength when combined with repair alone.<sup>18-20</sup> Multiple studies using a human cadaveric biomechanical model have shown that repairs augmented with acellular dermal allograft had significantly higher load to failure and less displacement with cyclic loading compared to nonaugmented repairs.<sup>18-20</sup> The combination of superior mechanical strength to minimize biomechanical failure while minimizing gap formation at the tendon-bone interface, and to improve the opportunity to integrate into the host tendon-bone interface, has a potential to improve rotator cuff healing in the near and long term.

In animal studies, the bioconductive nature of these acellular dermal allografts has also been established. In a canine model, the rotator cuff tendon was excised from the musculotendinous junction to the footprint and repaired with an acellular dermal allograft and compared to a control group where the native tendon was transected from the footprint and repaired primarily. By 12 weeks, the two groups had comparable load to failure strength and at 6 months, the experimental group had the histologic appearance of normal tendon with living tenocytes.<sup>21</sup> A similar finding of graft incorporation and histologic similarity to normal tendon was also shown in a rat model.<sup>22</sup> A rabbit model also demonstrated incorporation of the acellular dermal graft into the repair site, which resembled a normal tendon at 8 weeks.<sup>23</sup> A limitation of many nonprimate rotator cuff models is the inability to simulate chronic tears and diseased tendons. Additionally, the animal's inherent reparative capacity and ability to bridge a torn rotator cuff without augmentation or repair remain a criticism of these nonprimate models for translational human research. However, in 2008, Romeo et al. presented a study in a large primate model in which they demonstrated that subscapularis repair augmentation with acellular dermal allograft led to incorporation of the graft with intact tenocyte and histologic appearance of normal tendon.<sup>55</sup>

Clinical outcomes of graft augmentation during rotator cuff repair are in their early stages, but show promising data. The prospective blinded study by Gilot et al.<sup>24</sup> showed that ECM augmentation group had a lower retear rate compared to the control group (10% vs 26%, respectively), improved PROMs (visual analog scale, American Shoulder and Elbow Surgeons score, Short Form 12, and Ontario Rotator Cuff index). Avanzi et al.<sup>34</sup> performed a Level I randomized controlled trial for the use of graft augmentation in single-row rotator cuff repair, which showed a 2.4%

retear rate with graft augmentation compared to 40.5% retear rate in the control group. Taking all currently available data on clinical outcomes following graft augmentation, a meta-analysis by Bailey et al.<sup>26</sup> showed that ECM graft augmentation leads to lower retear rates and improved ASES scores compared to conventional repair alone.

Although the use of ECM augments during rotator cuff repair has strong potential to improve patient outcomes and decrease retear rates, like any new technology or technique, it is associated with incremental costs that should be considered in the context of the economic assessment. These costs, however, have the potential to lead to improved patient outcomes, QALYs, and decreased costs to the health care system in the long run. This is a field of considerable interest and enthusiasm, as a recent survey of British shoulder and elbow surgeons showed that 58% had previously used a graft for augmentation, with 70% of those in the previous 6 months, and 50% of the surgeons overall expressed an interest in participating in a randomized control trial on graft augmentation in the future.<sup>56</sup> ECM augmentation of rotator cuff repair has been shown in the literature to provide improved biomechanical properties and superior patient-reported outcomes and healing compared to conventional rotator cuff repair.<sup>24-26</sup> Despite its advantages, graft augmentation does come with increased operative time and technical demand. Further improvement in surgical techniques and implants specific for use with graft augmentation will likely decrease this burden.

In an era focused on decreasing health care costs and more efficient health care delivery, the message is clear: perform the proper surgery the first time with the greatest potential for improvement in patient outcomes. Identification of the proper surgical candidate with execution of the optimal surgery remains paramount for cost mitigation in the healthcare system. Any surgical procedure that has the potential to decrease revision procedures, increase QALY, and improve patient outcomes should be considered in the treatment algorithm for rotator cuff repair. The use of ECM graft augmentation has the potential to lead to improved healing rates of rotator cuff repairs, improved patient clinical and functional outcomes, and decreased rates of revision surgery, all while being considered cost effective. With larger tears or patients at higher risk of retear, ECM may prove to have even greater benefit, potentially becoming more cost-effective. However, given that payment processes in this country are largely based on direct costs of the episode of care, obtaining coverage for use of a graft remains challenging. Another hurdle that remains to its more widespread use remains the technical difficulties and learning curve associated with using a graft at the time of rotator cuff repair. Not unlike evolution and clinical adoption of

superior capsule reconstruction, the technical challenges associated with performing graft augmentation will require further clinical studies of optimal graft thickness/preparation, and the development of improved surgical instruments and delivery devices to make this a simpler technique, allowing more routine use where desired.

### Limitations

This cost-effective analysis has significant limitations. First and foremost, this remains a model of patient outcomes based on literature that is available, using multiple sources across a long period of time. Like all models, our results are only as good as the inputs used with them. This is a relatively young field with developing literature, and as more studies are published, our financial analysis can be further improved. Our study is based on the data from a single Level I study,<sup>34</sup> with the majority being Level IV studies.<sup>28,31,32,35</sup> The field of rotator cuff repair and graft augmentation is a heterogeneous field with few surgeries exactly like the other. Our analysis does not take into account tear size, or tear characteristics, such as fatty atrophy, patient age, and patient risk factors. Each of these has significant potential to affect the clinical outcome of rotator cuff surgery. Because of the paucity of literature currently available, particularly with regards to graft augmentation, our study could not take these factors into account.

### Conclusions

Graft augmentation does come with a significant upfront cost; however, on the basis of our decision-tree analysis, it may represent a cost-effective procedure. There is evidence to potentially consider increased use in rotator cuff repairs, while being cost effective.

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