Original Article

# Resorbable Bioinductive Collagen Implant Is Cost Effective in the Treatment of Rotator Cuff Tears

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**Purpose:** This study was conducted to investigate whether the use of resorbable bioinductive collagen implant (RBI) in addition to conventional rotator cuff repair (conventional RCR) is cost-effective when compared to conventional RCR alone, in the treatment of full-thickness rotator cuff tears (FT RCT). **Methods:** We developed a decision analytic model to compare the expected incremental cost and clinical consequences for a cohort of patients with FT RCT. The probabilities for healing or failure to heal (retear) were estimated from the published literature. Implant and healthcare costs were estimated from a payor's perspective in 2021 U.S. prices. An additional analysis included indirect cost estimations (e.g., productivity losses). Sensitivity analyses explored the effect of tear size, as well as the impact of risk factors. **Results:** The base case analysis demonstrated that resorbable bioinductive collagen implant + conventional rotator cuff repair results in incremental costs of $232,468 and an additional 18 healed RCTs per 100 treated patients over 1 year. The estimated incremental cost-effectiveness ratio (ICER) is $13,061/healed RCT compared to conventional RCR alone. When return to work was included in the model, RBI + conventional RCR was found to be cost saving. Cost-effectiveness improved with tear size with the largest benefit seen in massive tears compared to large tears, as well as patients at higher risk of retearing. **Conclusions:** This economic analysis demonstrated that RBI + conventional RCR delivered improved healing rates at a marginal increase in costs when compared to conventional RCR alone and is, therefore, cost-effective in this patient population. Considering indirect costs, RBI + conventional RCR resulted in lower costs compared to conventional RCR alone and is, therefore, deemed to be cost saving.

## Introduction

Rotator cuff disease describes an injury or a degenerative condition that results from damage to rotator cuff enthesis and is one of the leading causes of shoulder-related disability.[1-3] The incidence of cuff disease varies between 5 and 40%,[4] and is age related with increasing incidence for the elderly.[5-7] Cuff tear prevalence in each decade has been reported as 0% in the 20-49, 10.7% in the 50-59, 15.2% in the 60-69, 26.5% in the 70-79, and 36.6% in over 80%.[7] Another study found that the incidence was 9.7% for those aged less than 20 years and 82% for those aged over 80 years.[8]

Cuff disease can produce considerable pain and disability with substantial direct and indirect costs associated with treatment. Direct costs are those associated with the diagnosis and treatment of cuff pathology, while indirect costs include lost income due to inability to work, lower wages, missed work days, and disability payments.[9] One recent U.S. study assessed the burden of illness associated with RCT and estimated that the mean all-cause direct annual surgical costs were $34,086 for patients with partial-thickness tears and $34,249 for patients with full-thickness tears. There are further indirect costs associated with productivity losses due to absenteeism and short-term disability.[10]

Surgical cuff repair has been recommended for the treatment of symptomatic tendon tears with the aim of relieving the patients' pain and restoring the function of the shoulder joint, by reproducing native anatomy.[11] The ability to heal a cuff tear after surgery is impacted by age, hypertension, alcohol consumption, obesity,

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and other risk factors.[6] Healing and resolution of symptoms following arthroscopic repair also depend in part on underlying physiological factors, such as tendon vascularity, tissue quality, and footprint pathology.[12] There is a substantial biologic contribution to rotator cuff disease, which has generated interest in using biological augmentation to enhance the healing environment, including the use of scaffolds, such as resorbable bioinductive collagen implants.[13,14] Resorbable bioinductive collagen implants have been found to be safe and effective in the surgical treatment of both partial- and full-thickness tears,[13,15,16] and research is ongoing to gain further understanding of indications and optimal conditions for RBI use.

Despite the available clinical evidence for the performance of resorbable bioinductive collagen implants; however, surgeons need information to accurately weigh the potential costs versus benefits for patients. The purpose of this study was to investigate whether the use of RBI (REGENETEN, Smith & Nephew, Andover, MA), in addition to conventional RCR is cost-effective when compared to conventional RCR alone in the treatment of full-thickness rotator cuff tears (FT RCT). Our hypothesis was that when both direct and indirect costs of care are considered, rotator cuff repair with a resorbable bioinductive collagen implant would be more cost-effective compared to conventional cuff repair in patients with FT RCT.

## Methods

### Decision-Analytic Model

We developed a decision analytic model to compare the expected incremental cost and clinical consequences for a cohort of patients with full-thickness rotator cuff tears treated with conventional RCR compared with conventional RCR plus resorbable bioinductive collagen implant (RBI). Conventional rotator cuff repair for full-thickness tears was considered to be arthroscopic or open repair with either double-row, single-row or suture bridge technique.[17-20] The base case analysis considered medium, large, and massive tears together for a cohort of patients aged 58 years and then assessed individual tear sizes in sensitivity analysis. The mean age was chosen to reflect most patients included in the studies, which contributed to the clinical data. The schematic representation of the model is shown in Fig 1.

The treating physician has a choice of either managing the patient with conventional RCR alone or resorbable bioinductive collagen implant as an adjunct to conventional RCR. Following the treatment with either intervention, the RCT either heals or fails to heal (assumed to remain torn). Currently, there is controversy as to what constitutes healing or retearing in the literature, as it is difficult to tell whether a cuff has truly retorn, simply never healed, or some combination of both.[21] We adopted the definition that was used in Hein et al. (2015)[21] and Bushnell et al. (2021)[22] studies, which defined retearing as including rotator cuffs that have retorn after healing, as well as those that have not fully healed or failed to heal altogether postsurgery based on imaging studies magnetic resonance imaging, ultrasound, or arthrogram.[21,22]

Patients who failed to heal could undergo revision RCR surgery, reverse total shoulder arthroplasty, or received conservative management (e.g., pain management). In the base case, we report these tears sizes combined and then considered them separately in a scenario analysis. The analysis was conducted over a 1-year time horizon in line with the clinical data that was used in the model, and no discounting was necessary, as all costs and outcomes were assumed to occur in 1 year.

### Failure Rate

The probability of healing was dependent on the tear size. The probability of a FT RCT failing to heal with conventional RCR was obtained from a systematic review of literature by Hein et al. (2015), assessing arthroscopic single-row, double-row, or suture bridge rotator cuff repair[21] and a randomized controlled trial by Rashid et al. (2017),[23] which used both open and arthroscopic techniques. For this analysis, we extracted data on medium, large, and massive tears treated arthroscopically to mirror the population, tear size, and surgical technique of the comparator studies. The study by Rashid et al. (2017)[23] also reported retear rates in 256 patients by tear size in the United Kingdom. For patients treated with RBI, the probability a full-thickness tear failing to heal was obtained from a multicenter registry study using the implant[11] and three prospective studies.[15,22,24] The base model combined the retear rates reported in all four studies, and in all cases, 12-month data were used in the model (Table 1).

The probability of having a revision, reverse total shoulder arthroplasty, or conservative management following a tear recurrence was taken from the IBM Watson Health MarketScan Commercial database, which found that 25.22% and 3.9% would either have a revision surgery defined as reoperation surgery on index shoulder or reverse shoulder arthroplasty, respectively.[10] The MarketScan databases include the patient-level paid and adjudicated medical and pharmacy claims in all care settings, including physician office visits, hospital stays, and outpatient prescription pharmacy claims. We then assumed the remainder (70.9%) of the patients would be managed using conservative methods.

### Resource Utilization, Unit Costs, and Indirect Costs

Resource use data and cost information were obtained from the published literature. Physiotherapy

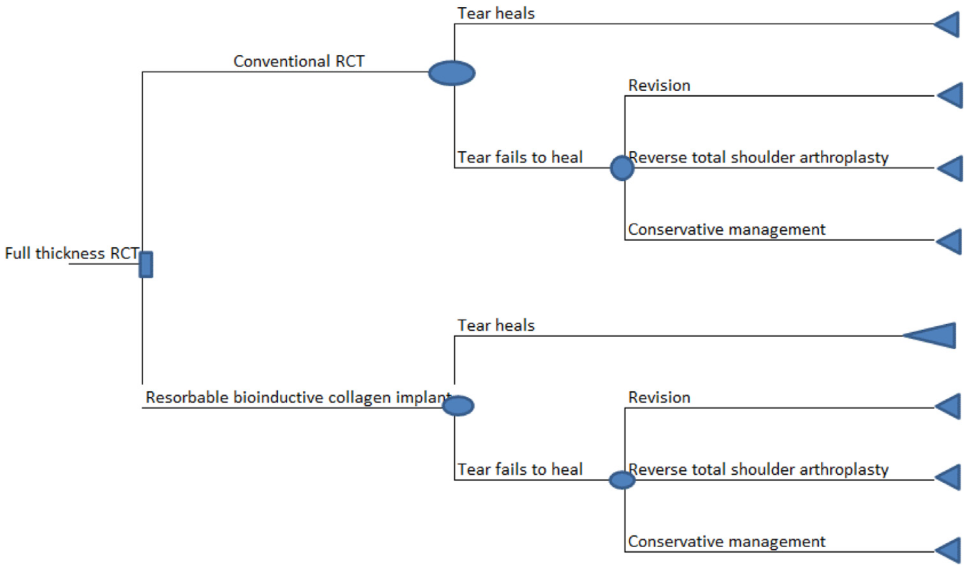


**Fig 1.** Model structure (decision analytic model) for resorbable bioinductive collagen implant plus conventional rotator cuff repair (RCR) compared to standard of care alone in full-thickness RCT.

following shoulder repair surgery is considered a standard intervention. The average number of physiotherapy appointments after conventional RCR is 27,[25] while patients who undergo RBI + conventional RCR have an average of 22 appointments.[11,22] In the model, we assumed there was no difference in physiotherapy appointments and, therefore, applied the average of the 3 studies, which is 24.5 appointments. The cost of physiotherapy session per hour was estimated from a published study.[10]

The cost of failure to heal was based on costs relating to revision, reverse total shoulder arthroplasty, and

**Table 1.** Data Used in the Model

| Health state and Intervention costs | Value | Lower CI | Upper CI | Reference |
|---|---|---|---|---|
| Revision cost | $13,118 | $10,494 | $15,742 | 10 |
| Reverse total shoulder arthroplasty | $37,500 | $30,000 | $45,000 | 10 |
| Societal cost workers compensation per week (median wage) | $990 | $792 | $1,188 | 28 |
| Incremental implant cost | $3,641 | | | |
| Resource impact (physiotherapy sessions per patient) | | | | |
| Conventional rotator cuff repair | 25 | 20 | 30 | 11,22,25 |
| Resorbable bioinductive collagen implant | 25 | 20 | 30 | |
| Return to work in weeks | | | | |
| Conventional rotator cuff repair | 14 | 11.2 | 16.800 | 26,27 |
| Resorbable bioinductive collagen implant | 6.91 | 5.531 | 8.297 | 11 |
| Conventional rotator cuff repair retear rates | | | | |
| Medium | 0.190 | 0.152 | 0.227 | 21,23 |
| Large | 0.287 | 0.230 | 0.345 | |
| Massive | 0.501 | 0.401 | 0.601 | |
| Combined | 0.271 | 0.217 | 0.325 | |
| Resorbable bioinductive collagen implant retear rates | | | | |
| Medium | 0.072 | 0.057 | 0.086 | 11,15,22 |
| Large | 0.119 | 0.095 | 0.142 | 11,22,24 |
| Massive | 0.0930 | 0.074 | 0.112 | 11,22,24 |
| Combined | 0.0928 | 0.074 | 0.111 | |
| Events following retear/failure | | | | |
| Revision surgery | 0.252 | 0.202 | 0.303 | 10 |
| Reverse total shoulder arthroplasty | 0.039 | 0.031 | 0.047 | 10 |
| Conservative management | 0.709 | 0.598 | 0.897 | |
| Risk factors for retearing | | | | |
| Age >60 years | 2.12 | 1.44 | 3 | 6 |
| Hypertension | 2.05 | 1.41 | 2.98 | |
| Alcohol consumption | 2 | 1.4 | 2.9 | |
| Obesity | 2.4 | 1.4 | 3.76 | |

**Table 2.** Base Case Results for Resorbable Bioinductive Collagen Implant Compared to Conventional RCR, Results Expressed per 100 Treated Patients

| Intervention | Total Cost | Tears Healed | Difference in Costs | Difference in Healed Tears | Cost per Healed Tear |
|---|---|---|---|---|---|
| Conventional rotator cuff repair | $322,126 | 73 | | | |
| Resorbable bioinductive collagen implant | $554,594 | 91 | $232,468 | 18 | $13,061 |

conservative management. Revision and reverse total shoulder arthroplasty costs were based on the study by Parikh et al. (2021).[10] Conservative management costs were taken from the same study and were based on outpatient office visits, physiotherapy visits, and nonsteroidal anti-inflammatory drugs (NSAID) to manage pain.[10]

One of the main concerns following rotator cuff surgery is the time it takes for patients to get back to their activities of daily living and work. In a scenario analysis, our model took into consideration costs of taking time off work due to rotator cuff injury. Data relating to the number of weeks off work for conventional RCR were calculated from Acevedo et al. (2014).[26] The authors found that return to work was 1 to 2 weeks for sedentary jobs and 4 to 6 months for manual labor jobs. A meta-analysis by Haunschild et al. (2021)[27] found that among workers who returned to work following RCR, 29%, 23%, and 47% performed low, moderate, and heavy work, respectively. We used these data from Haunschild et al. and Acevedo et al. to estimate the weighted number of weeks that it took people to return to work with conventional RCR to be 14 weeks. For the resorbable bioinductive collagen implant, the study by McIntyre et al. (2021)[11] estimates 7 weeks, while the study by Bushnell et al. 2022[22] estimated 6.3 weeks for full-thickness tears, respectively. However, both studies did not report results by type of work (manual or sedentary) performed by study participants. The impact of return to work was subsequently converted into costs by using the average weekly pay in the United States taken from the Bureau of Labor Statistics 2021.[28]

Since the model assumes that RBI is used as an adjunct to conventional RCR, conventional RCR cost was assumed to be the same in both arms of the study, and only the incremental cost of the RBI surgery was considered. All costs, resource use, and clinical data used in the model are presented in Table 1.

The base case analysis was conducted from the U.S. payer's perspective. We also evaluated the model from a societal perspective. The societal perspective captures benefits associated with all stakeholders: patient, employee, and insurer, which results in optimal decision making, especially for regulatory and reimbursement decisions.[29,30]

### Cost-Effectiveness and Sensitivity Analysis

The difference in costs (the incremental cost) was calculated as the total cost for RBI + conventional RCR, minus the total cost for conventional RCR alone and, similarly, the difference in effectiveness was calculated as the difference in healed tears at 1 year. The incremental cost-effectiveness ratio (ICER) of the RBI + conventional RCR relative to conventional RCR was calculated as the difference in costs between the interventions divided by the difference in healed tears over 1 year.

Considering uncertainty is an important part of an economic evaluation. Sensitivity analyses helps identify which variables have the most impact on the results and, therefore, attempts to test the model under different conditions to determine the validity of the conclusions. We conducted a one-way we did not conduct probabilistic sensitivity analysis sensitivity analyses. For this one-way sensitivity analysis, we varied inputs one at a time using the data reported in the literature. Where such data were not reported, we varied each model input by ±20%, as is the case in most economic evaluations when no data are reported. Furthermore, we conducted a scenario analysis where we evaluated the impact of risk factors for rearing such as age, hypertension, obesity, and alcohol consumption on the cost effectiveness of results.

## Results

### Base Case Analysis

The base case analysis demonstrated that RBI results in improved healing/retear rates, with more patients achieving a successfully healed rotator cuff, at an increase in cost. The estimated incremental cost effectiveness ration of RBI was $13,061 per additional healed tear (see Table 2).

**Table 3.** Scenario Including Impact of Interventions on Indirect Costs, Results Expressed per 100 Treated Patients

| Intervention | Total Cost | Tears Healed | Difference in Costs | Difference in Healed Tears | Cost per Healed Tear |
|---|---|---|---|---|---|
| Conventional rotator cuff repair | $1,708,126 | 73 | | | |
| Resorbable bioinductive collagen implant | $1,239,108 | 91 | -$469,017 | 18 | Dominant* |

*Dominant means resorbable bioinductive collagen implant + conventional rotator cuff repair is cheaper overall and results in improved healing rates.

**Table 4.** Assessing the Impact of Interventions on Tear Sizes, Results Expressed per 100 Treated Patients

Impact of interventions on tear sizes on model results

| Tear Size | Difference in Costs | Difference in Healed Tears | Cost per Healed Tear |
|---|---|---|---|
| Base case results | $232,468 | 18 | $13,061 |
| Medium | $277,081 | 12 | $23,550 |
| Large | $239,339 | 17 | $14,188 |
| Massive | $62,242 | 41 | $1,525 |

Impact of retear risk factors on model results

| Risk factors | Difference in Costs | Difference in Healed Tears | Cost per Healed Tear |
|---|---|---|---|
| Age greater than 60 | $85,052 | 38 | $2,254 |
| Hypertension | $94,266 | 36 | $2,584 |
| Alcohol consumption | $100,847 | 36 | $2,833 |
| Obesity | $48,198 | 43 | $1,128 |

### Scenario Analysis, Including the Impact of Interventions on Indirect Costs

When the impact on return to work was included, RBI as an adjunct to conventional RCR was found to be cost saving compared to conventional RCR alone, saving $469,017 per 100 treated patients with FT RCT. A cost-saving strategy results in lower treatment costs overall and improved healing rates (see Table 3).

### Assessing the Impact of Tear Sizes on the Results

When analyzed by tear size, the results show that the cost effectiveness of RBI improves with increasing size of tear (see Table 4).

### Impact of Risk Factors for Retearing

We assessed the impact of some of these factors on the model results and observed that patients with characteristics that reduce healing rates benefited from RBI. RBI improved healing rates in those conditions compared to the base case, in which risk factors were not included (see Table 4).

### One-Way Sensitivity Analysis

The one-way sensitivity analysis results are shown in Fig 2 as a tornado diagram. The extremes of each range represent the ICER associated with ±20% variation in each of the variables. The results are portrayed in decreasing order of the variable's impact on the ICER. The probability of failure to heal or retear rate of the standard of care had the greatest impact on the ICER, followed by the effectiveness of RBI.

## Discussion

Results of the economic model shows that RBI delivers improved healing rates at an incremental cost. The inclusion of indirect costs (return to work) in the analysis predicted that RBI would deliver improved healing rates at lower treatment cost than conventional surgery. Further analyses indicated that RBI becomes more cost effective in patients with larger tears and in those at risk for lack of healing or retearing.

In today's healthcare environment, it has become increasingly important to demonstrate that new

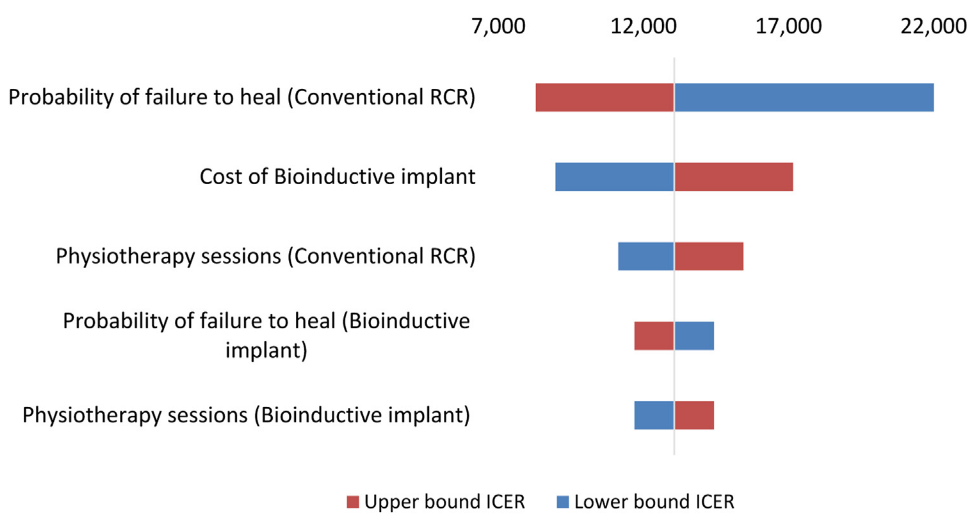


**Fig 2.** Tornado diagram showing impact of individual parameters on the estimated incremental cost-effectiveness ratio for resorbable bioinductive collagen implant compared to conventional rotator cuff repair, i.e., one-way sensitivity analysis varying model inputs between the reported low and uppermost values.

technologies provide financial value. One way of making better informed decisions about the value of new devices is adopting cost-effectiveness analysis. Although many promising technologies deliver improved outcomes, it is also important to determine at what cost and whether the incremental cost is justifiable.

The inclusion of indirect costs in economic evaluations is controversial. Early guidelines for economic evaluation recommended adopting a societal perspective, which considers all costs and outcomes.[29,31] A social perspective ensures that the costs of all services associated with providing care to patients, regardless of who bears the costs, are included. Indeed, the study by Mather et al. (2013)[9] and Vitale et al. 2007[32] both used a societal perspective in their analysis of RCR compared to nonsurgical techniques. However, Mather et al. included productivity costs, i.e., return to work and concluded that RCR was overall cost-saving, while Vitale et al. did not include productivity costs and concluded that RCR was cost-effective compared to nonsurgical techniques. In the United States, it is estimated that about 2 million people suffer from a nonfatal work-related injury, resulting in time away from work and compensation payments of nearly $40 billion per year.[33] It would be beneficial to payors, patients, and employers to pay for interventions that can facilitate earlier return to work.

Similarly, we adopted this more comprehensive approach and included direct costs, as well as productivity costs (return to work) associated with the treatment of RCR to better estimate the value of RBI treatment. This approach is justified since, in many cases, cuff pathology occurs in people of working age and can result in a lengthy period of inactivity and lost productivity. Such an analysis demonstrated that rotator cuff tears are associated with both a substantial treatment and broader societal cost and that the use of RBI is associated with cost savings of nearly half a million dollars in 100 treated patients. However, we acknowledge that additional evidence is needed to ascertain this finding. Payment coverage decisions now reside with third-party payors and providing them with proof of safety, efficacy, and superiority regarding cost should have the goal of improving patient access to successful treatments and new technology.

Innovation is the hallmark of improving patient care. Introducing novel products that improve healing rates, decrease complications, and facilitate recovery are essential to improvements in treating all musculoskeletal conditions. In this analysis, RBI delivered improved healing/retear rates but at an increased direct healthcare treatment cost. In situations such as these, it is important that healthcare providers can identify those patients who may benefit the most from the new interventions to justify the incremental costs. Our analysis illustrated that those patients with larger tears and those with risk factors for adverse outcomes would experience lower cost per healed tear with use of the RBI. This is not a surprising finding, as people at increased risk of retearing have an increased baseline risk, yet we assume the impact of RBI treatment remains the same, which increases the number of healed tears, making the denominator large. A larger denominator will result in a more favorable cost-effectiveness ratio that is a smaller one or even cost-saving finding. For decision makers with responsibility for resource allocation, information such as this can help to identify how new technologies can be made available to patients in the most cost-effective manner to maximize outcomes.

## Limitations

Our study has limitations. First, we made some simplifying assumptions, such as restricting the analysis to 12 months postsurgery. We acknowledge that in practice, retear may appear after 12 months. However, if this is the case, we believe this analysis will be conservative, as it may bias the results against RBI, which is expected to reduce the incidence of failure long term. Currently, we are awaiting long-term data to validate this hypothesis. We also assumed that risk factors that influence retear or failure rates are independent. Patients often present with multiple risk factors, such as diabetes and hypertension. Furthermore, we used data from noncomparative studies for RBI; however, we are aware of a randomized controlled study comparing RBI to conventional RCR, which has reported promising interim results showing 86% reduction in nonhealing rates in favor of RBI in 59 patients presented as a conference proceeding.[34] Our economic evaluation utilized noncomparative single-arm studies to estimate the impact of RBI when compared to conventional RCR, showing a 66% reduction in non-healing RCT which is less than what the interim results are showing, suggesting our analysis used conservative estimates of the potential impact of RBI. The studies for RBI, which provided evidence on return to work did not report by type of work (sedentary or manual). This information should be collected and be reported separately in future studies. We suggest updating our study once further comparative evidence becomes available. Furthermore, additional comparative evidence addressing return to work is needed segmented by occupational type, for instance, sedentary or manual.

## Conclusion

This economic analysis demonstrated that RBI + conventional RCR delivered improved healing rates at a marginal increase in costs when compared to conventional RCR alone and is, therefore, cost-effective in this patient population. Considering indirect costs, RBI +

conventional RCR resulted in lower costs compared to conventional RCR alone and is, therefore, deemed to be cost saving.

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