REVIEW

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The Clinical Efficacy of the Regeneten Bioinductive Implant in Rotator Cuff Repair: A Systematic Review

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Despite advancements in surgical techniques for rotator cuff repair, retear rates remain a significant concern. This study systematically reviews the evidence on the effectiveness of the Regeneten Bioinductive Implant in improving healing outcomes. A systematic review of the literature was conducted by searching on PubMed, Embase, Web of Science Core Collection and Cochrane Library. Studies reporting on effectiveness, safety, radiological, clinical outcomes, or patient-reported outcomes after Regeneten use, with at least 12 months of follow-up, were considered. 17 articles were included in this review, encompassing data on 1062 rotator cuff tears, of which 966 were treated with Regeneten. The implant use resulted in retear rates of 0% up to 18% after 5 years in PT tears and 0% up to 35% after 2 years in FT tears. In 1 randomised trial, the retear rate was significantly lower in the implant group compared to the control group. Constant-Murley Score (CMS) and the American Shoulder and Elbow Surgeons (ASES) score showed a sustained improvement compared to pre-operative scores across all studies. MRI showed increased tendon thickness starting from 6 months, with MRI signals suggesting that the implant was integrating with the native tendon and becoming indistinguishable. While using Regeneten for rotator cuff tears of various sizes and chronicity is associated with reduced retear rates in some studies, the clinical outcomes remain within the same range as those seen with traditional rotator cuff repair. Additional randomized controlled trials are required to validate these results and clarify the appropriate indications for using this implant.

Keywords: Rotator cuff tear, rotator cuff repair, augmentation, Regeneten, bioinductive implant, collagen implant.

INTRODUCTION

Rotator cuff tears (RCTs) represent a significant challenge in orthopaedic surgery, affecting individuals across a wide spectrum of ages and activity levels. They are present in 13% to 54% of the general population, with the frequency increasing considerably among those over 60 years old[1]. These injuries, whether stemming from acute trauma or degenerative processes, can profoundly impact shoulder function, leading to pain, weakness, and functional limitations[2-4].

If attempts at conservative management are unsuccessful, surgical intervention offers a reliable treatment option[5]. The goal of surgical intervention is to facilitate the healing process and promote the optimal biomechanical function of the shoulder joint[7]. Rotator cuff repair involves various surgical techniques, including arthroscopic, open and mini-open methods, tailored to the specific characteristics of the tear, the patient's needs and the surgeon's preference[7-9].

Despite major advances made in surgical techniques, retear rates ranging from 3.3% to 50% has remained a main issue after rotator cuff repair[10,11] Insufficient biological healing, influenced by smoking and nutritional status, at the tendon-bone interface is described as a contributing factor to early retears, alongside factors like muscle fatty infiltration and surgical technique[12]. The size of the tear and the quality of the tissue also have been shown to significantly influence the reported healing rates of rotator cuff tears[13]. Numerous studies have established that despite radiological failures, characterized by tendon healing failure or re-tears, many patients still experience favourable clinical outcomes after repair[14]. However, compelling evidence also suggests that individuals with well-healed tendons tend to achieve superior clinical results and better patient-reported outcome measures (PROMs)[11,15,16].

The weakest aspect of the modern RCR construct resides in the tissue-suture interface[17]. In recent years, there has been a continued search for methods to improve retear rates following rotator cuff repair further, with implant augmentation emerging as a popular approach in addressing this challenge. This approach involves reinforcing the tendon repair construct with either biological (animal-derived or human-derived) or synthetic implants, thereby enhancing its mechanical strength and promoting more robust healing. The objective behind employing implant augmentation in rotator cuff repair is to aid in tissue integration by promoting vascularization and stimulating the growth of native tissue, while offering biomechanical reinforcement and creating an ideal environment conducive to rotator cuff healing[18,19]. Orthopaedic surgeons have various scaffold devices at their disposal for rotator cuff repair, with each distinct physical, chemical, and biological properties. These factors are crucial considerations in selecting the most suitable device for each individual case of rotator cuff repair[20].

Several systematic reviews and meta-analyses in the literature offer mixed levels of evidence for implant augmentation in RCR, frequently combining different implants into a single analysis. This complicates the assessment of each implant's utility[19,21,22]. Therefore, the aim of our paper is to focus on one specific implant, the Regeneten Bioinductive Implant. It was initially introduced to the market by Rotation Medical and is currently being distributed by Smith and Nephew (Andover, MA). Regeneten is a highly porous, bioinductive implant fashioned from highly purified type I collagen sourced from bovine Achilles tendon. It serves as a porous framework, facilitating the adhesion of regenerative cells and the exchange of nutrients and waste[23-24]. This paper aims to analyse the efficacy and safety of using the Regeneten implant for rotator cuff repair.

MATERIALS AND METHODS

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[25,26]. Adhering to the PRISMA 2020 checklist, multiple databases were systematically searched for relevant studies, titles and abstracts were screened, full-text articles were assessed for eligibility, and data was extracted using predefined criteria. Additionally, the Cochrane Handbook for Systematic Reviews of Interventions was used to guide the development and writing of this review[27].

Data Sources and Search Strategy

Our search strategy encompassed PubMed (including Medline), Embase, Web of Science Core Collection, and the Cochrane Library databases for relevant studies. 'Rotator cuff tears' and 'bioinductive collagen implants' were used as the two main concepts for the design of our search strategy. The precision of our search strategy was tested with a few articles evaluating the Regeneten implant. By checking whether these articles were detected with our search strategy, it could be evaluated if the strategy was extensive enough. In addition, searches were conducted on the trials registers ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) portal to gather information about completed, terminated, and ongoing trials. The literature search was carried out on 06/06/2024 for all the databases and registers.

Eligibility Criteria

Inclusion criteria encompassed human studies investigating the use of the Regeneten bioinductive collagen implant (Smith and Nephew®). Studies where Regeneten was used for rotator cuff repair, were considered. Systematic reviews, randomized controlled trials, cohort studies, case-control studies, and case series involving participants of any age or sex, with an acute or chronic, partial or full-thickness rotator cuff tear were included. Studies were considered if they reported outcomes related to effectiveness, safety, histological, radiological, clinical outcomes, or patient-reported outcomes, with a minimum follow-up duration of 12 months. Economic analyses were also included, only for economic evaluation of the implant.

Exclusion criteria comprised animal or in vitro studies, duplicate publications, non-English language studies, narrative reviews, editorial commentaries, and those with high risk of bias or methodological flaws. Studies with inadequate follow-up (< 12 months) or focusing on superior capsular reconstruction were also excluded.

Screening process

The articles were initially deduplicated. Afterwards the screening process, which consisted of two rounds, was carried out by one reviewer, MB. The first screening was conducted using only the titles and abstracts of the articles. Second screening consisted of selecting articles that met the inclusion criteria, based on full texts of the articles. In cases of uncertainty, two independent reviewers, PD and FV, were consulted

for their input. The screening process was facilitated by the online tool Rayyan[28].

Quality Assessment

The quality of randomized controlled trial reports in our systematic review was assessed using the Jadad Scale[29]. The National Heart, Lung, and Blood Institute (NHLBI) quality assessment tool was used to evaluate the included case series studies[30]. The systematic reviews were evaluated using the AMSTAR 2 tool[31].

Outcomes

The aim of this systematic review was to discuss the following outcomes: retear rate, radiological outcomes, histological outcomes, patient-reported outcomes (PROs), and clinical outcomes measuring force and mobility, including the Constant-Murley Score (CMS), American Shoulder and Elbow Surgeons (ASES) score, Visual Analog Scale for pain (VAS-pain), EuroQol 5-Dimension 5-Level (EQ-5D-5L), Single Assessment Numeric Evaluation (SANE), Veterans RAND 12-Item Health Survey physical component (VR-12 physical component), and Western Ontario Rotator Cuff Index (WORC). Complications rate and economic evaluation were also reported as secondary outcomes.

Statistical analysis

A meta-analysis was not feasible due to the clinical heterogeneity among the reviewed studies. The variability was evident in the types of rotator cuff tears addressed, the use of the implant and the follow-up terms. Instead of a meta-analysis, a comparison of the studies was carried out for each outcome separately.

RESULTS

Screening, eligibility assessment and data extraction

A total of 8,259 articles were identified from the search performed on 06/06/2024. After deduplication, 4500 articles remained. During the first screening, which was based on title and abstract only, 119 articles were found to meet the eligibility criteria. Among these, 21 reports were not retrieved, including 9 ongoing studies. 98 articles underwent a second screening and were assessed for eligibility, using the full texts. 17 articles were identified as eligible for this systematic review. 51 reports were excluded due to incorrect or unspecified implants, while 9 articles were excluded because they focused solely on the technique of RCR. 1 article was excluded, as the Regeneten implant was used as a treatment of lateral epicondylitis. 15 articles were excluded due to incorrect publication type, such as editorial commentaries. 5 articles did not meet the criterion of a minimum of 12 months follow-up. Figure 1 illustrates the study selection process in a flow diagram, adhering to the PRISMA protocol[25].

Quality assessment

Table I shows the quality assessment. All the case series scored a minimum score of 6 on the NHLBI quality assessment tool for case series studies, with an average score of 7,33. Quality assessment of the cost-effectiveness analyses was differed as they were only used for economic analyses and were not taken into account for analysis of other (clinical) outcome.

Patient demographics

The systematic review included in our analysis 34 examined five studies also included in this study[36,37,43,45,47].To avoid data duplication, only the data of the original studies were used for analysis. Three of the included articles[37,40,45] describe the preliminary results of studies, while the final results are detailed in three other included articles[38,41,46]. This review included data on 1062 rotator cuff tears (in a total of 1062 patients) comprising 604 males and 458 females (Table II). Regeneten was implanted in 966 patients, the other 96 patients were controls in the RCT's. The mean age was 55,57 years. Of the 1062 rotator cuff tears, 635 involved full-thickness tears, and 427 involved partial-thickness tears. Of the full-thickness tears, 2,8% were small (< 1 cm), 59,9% were medium-sized (1-3 cm), 27,6% were large (3-5 cm or 2-tendon tears) and 9,7% were described as massive tears (> 5 cm or 3-tendon tears). Location of the PT tears is described in Table II; in 362 cases location of the tear was not reported. The majority of the tears were chronic (67%), with a smaller portion of acute and acute-on-chronic tears.

Surgical technique and use of the implant

The surgical techniques used for rotator cuff tear repairs were summarized, specifically focusing on the use of the bio-inductive implant for augmentation versus stand-alone repairs (Table I). The Regeneten implant was used for FT tears in 7 articles, for PT tears in 5 articles and for both in 2 articles (not taking into account the systematic review and cost-effectiveness analyses). In general, FT tears were treated with a classic repair followed by a bioinductive augmentation of the repair, and PT tears treated with a stand-alone implant placement without classic RCT repair, with 2 studies deviating from this. Camacho et al. treated

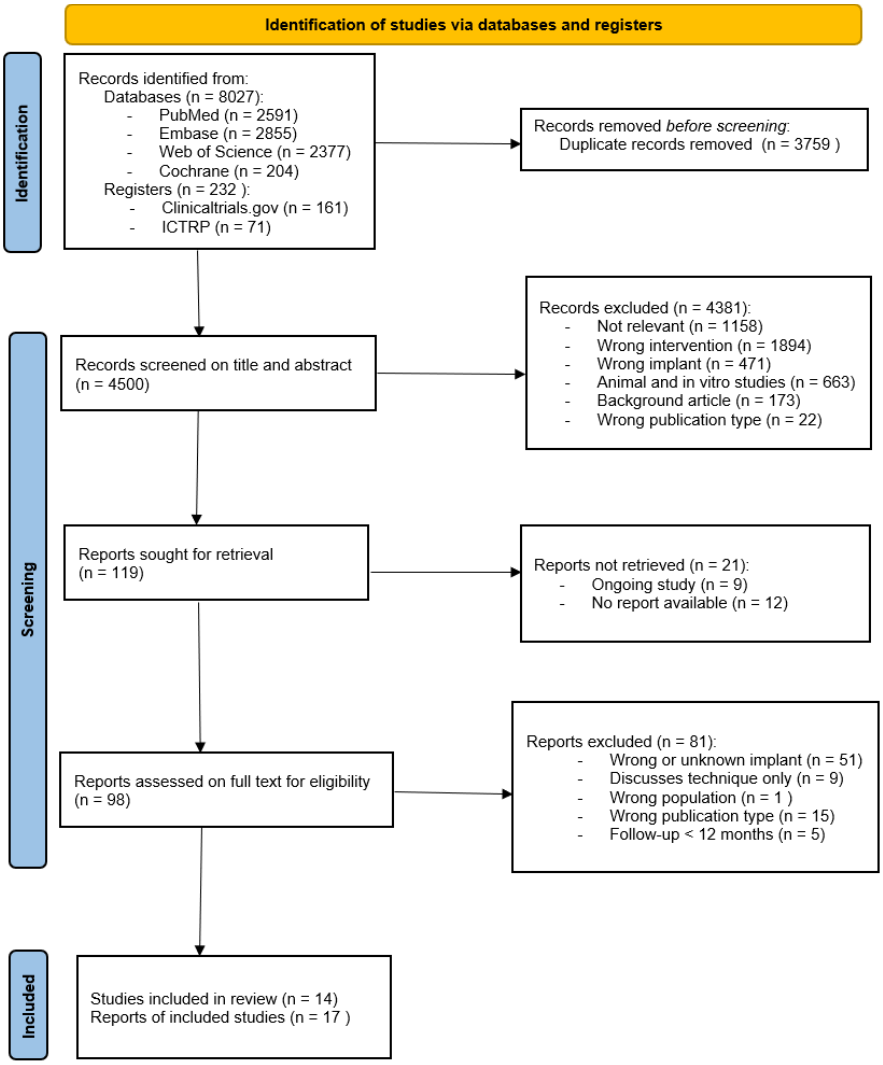

Fig. 1 — Prisma flow diagram.[32]
n= sample size.

FT tears with a stand-alone implant placement: the tear was debrided, and the bioinductive collagen implant (BCI) was positioned over it, extending across the bone-tendon junction[33]. Bushnell et al. treated PT tears in 241 patients with an isolated bioinductive repair, while 31 patients had their tears completed and repaired followed by bioinductive augmentation[39]. The procedures were performed arthroscopically in all articles except in one, where 5 cases were done arthroscopically and 4 via a mini-open approach.36 FT tear repairs were completed using either a double or single row technique in all the articles, according to the preference of the treating surgeon, though the majority of the tears were repaired with a double row technique.

Clinical outcomes and PROM

Table III summarizes the clinical outcomes and PROM's for the included articles. In the majority of studies, clinical outcomes were measured primarily using the Constant-Murley Score (CMS), the American Shoulder and Elbow Surgeons (ASES) score, and the Visual Analog Scale (VAS). The minimal clinically important difference (MCID) for the respective outcomes was determined based on existing literature, and the proportion of patients achieving MCID at specific time points during follow-up was evaluated. MCID for both ASES and CMS were achieved in a significant proportion of patients, varying across studies. CMS pain and ASES pain also showed significant improvement. Camacho et al. reported no statistical differences between FT and PT tears in the improvement of VAS, ASES and CMS at 6 months and 1 year[42]. In PT tears, tear location (articular, bursal, and intrasubstance) was found not to have any statistically significant impact on ASES or CMS scores at any follow-up points[45,46]. Unlike Ruiz Ibán et al. who report no

Table I. — Summary of included articles.

Author, year	Study design, evidence level	Quality	Patients (n)	Mean FU (months)	Extent of tear	Implant use	Retear rate	Complications
Priyavadhana S, 2021 [34]	Systematic review, I	AMSTAR 2: Low	251	12-24	FT & PT	See separate studies below	See separate studies below	See separate studies below
Camacho Chacón JA, 2024 [33]	RCT, I	Jadad 5/5	60 (30 controls)	24	FT	Implant group: stand-alone repair Control group: classic RCR	24 months postoperative: Control group: 0/30 (0%) Implant group: 0/30 (0%)	Post-surgical arthrofibrosis: 1 in implant group, 2 in control group
Ruiz Ibán M, 2024 [35]	RCT, I	Jadad 5/5	124 (63 controls)	12	FT	Implant group: repair augmentation Control group: classic RCR	12 months postoperative Control group: 16/63 (25,8%) Implant group: 5/60 (8,3%) P = 0,0106 with OR = 0,261	2 deep infections (1 from each group) 2 superficial infections (1 from each group) 2 early repair failure (2 in control group) 1 displaced implant
Bokor DJ, 2015 [36]	Prospective case-series, IV	NHLBI 8/9	9	25,8	FT	Repair augmentation	24 months postoperative: 0/9 (0%)	None
Bokor DJ, 2016 [37]* Bokor DJ, 2019 [38]*	Prospective case-series, IV Prospective case-series, IV	NHLBI 8/9 NHLBI 8/9	13 11	27 60,3	PT	Stand-alone repair	24 months postoperative: 0/13 (0%) 5 years postoperative: 2/11 (18%)	1 intra-operative shoulder swelling 1 adhesive capsulitis 1 long head biceps tendon rupture 1 bursitis
Bushnell BD, 2021[39]	Prospective case series, IV	NHLBI 6/9	272	12,7	PT	241 Stand-alone repairs, 31 repair augmentations	12 months postoperative: 3/272 (1,1%)	None
Bushnell BD, 2021[40]** Bushnell BD, 2022[41]**	Prospective case-series, IV Prospective case-series, IV	NHLBI 8/9 NHLBI 7/9	115 104	12 25	FT	Repair augmentation	24 months postoperative: Medium tears: 7/61 (11,5%) Large tears: 14/40 (35,0%) P = 0,0044	1 superficial infection 1 case of intermitting pain with inflammatory changes on MRI
Camacho Chacón JA, 2022 [42]	Prospective case-series, IV	NHLBI 7/9	30	12	FT & PT	FT: repair augmentation PT: stand-alone repair	12 months postoperative: FT: 0/12 (0%) PT: 0/18 (0%)	Capsulitis: amount of cases not reported
McIntyre LF, 2019 [43]	Retrospective case-series, IV	NHLBI 7/9	173	12	FT & PT	FT: repair augmentation PT: stand-alone repair	12 months postoperative: FT: 3/83 (3,6%) PT: 1/90 (1,1%)	1 infection 2 adhesive capsulitis 1 bursitis
McIntyre LF, 2021 [44]	Prospective case-series, IV	NHLBI 7/9	210	12,6	FT	Repair augmentation	12 months postoperative: 11/210 (5,2%) (at baseline: 5 medium tears, 3 large tears, 3 massive tears)	3 infections 3 adhesive capsulitis 1 bursitis

Table I. — Summary of included articles- part 2.

Author, year	Study design, evidence level	Quality	Patients (n)	Mean FU (months)	Extent of tear	Implant use	Retear rate	Complications
Schlegel TF, 2018 [45]***	Prospective case-series, IV	NHLBI 7/9	33	12,4	PT	Stand-alone repair	24 months postoperative: 1/33 (3%)	1 increased accumulation of subacromial fluid 1 stitch abscess
Schlegel TF, 2021 [46]***	Prospective case-series, IV	NHLBI 8/9	31	25,5				
Thon SG, 2019 [47]	Prospective case-series, IV	NHLBI 7/9	23	24	FT	Repair augmentation	24 months postoperative: 1/23 (4%)	8 cases of scapular dyskinesia 1 case of progressing pain and dysfunction
McIntyre LF, 2023 [48]	Cost-effectiveness analysis, IV				FT			
Rognoni C, 2023 [49]	Cost-effectiveness analysis, IV				FT			

Table II. — Characteristics of patients in included studies.

N patients	1062
N rotator cuff tears	1062
N Regeneten used	966
Gender	
Male (%)	604 (57)
Female (%)	458 (43)
Mean age (range)	55.57 (24-90)
Extent of tear	
Full-thickness (%)	635 (60)
Partial-thickness (%)	427 (40)
Bursa-sided	18
Articular-sided	20
Intra-substance	19
Hybrid	8
Not reported	362
Chronicity of tear	
Chronic (%)	716 (67)
Acute (%)	209 (20)
Acute-on-chronic (%)	114 (11)
Unknown (%)	23 (2)

Table III. — Summary of clinical outcomes and PROMs.

Study	Clinical outcomes and PROMs
	Full-thickness
Camacho Chacón JA, 2024 [33]	ASES and CMS significantly higher in the implant group throughout FU period VAS-Pain: No difference between groups at 24 months At 6 months: 100% of Regeneten patients and 96.7% of control patients met the MCID for the ASES score, 100% of Regeneten patients and 16.7% of control patients met the MCID for the CMS score
Ruiz Ibán M, 2024 [35]	General improvements pain levels, EQ-5D-5L, ASES and CMS in both groups, but no differences between groups during the FU in pain levels, CMS, ASES score, or EQ-5D-5L at any time point No differences in rates of MCID met for CMS and ASES score between both study groups (respectively 76,7% for Regeneten vs 81,7% for Control, p = 0,654 and 75% for Regeneten vs 80% for Control, p=0,829)
Bokor DJ, 2015 [36]	CMS pain score: Improved from 7,1 to 1,1 (p < 0,001) ASES pain score: Improved from 4,9 to 0,7 (p < 0,001) CMS: Improved from 50,7 to 78,0 (p < 0,001) ASES: Improved from 44,6 to 87,8 (p < 0,001)
Bushnell BD, 2021[40] 2022[41]	Significant improvements in ASES and CMS scores from the baseline to 1 year and 2 years (p < 0,001 for both) MCID for ASES and CMS was met at 1 year by 91,7% and 86,4% of patients, respectively
Camacho Chacón JA, 2022 [42]	Significantly improved VAS, ASES and CMS score at 6 months and 1 year
McIntyre LF, 2019 [43]	Significant improvement VAS, SANE, VR-12 physical component, ASES, and WORC over 12 months (p <0,05) MCDI for VAS pain and ASES was met by 72% and 77% of patients, respectively
McIntyre LF, 2021 [44]	Significant improvement in SANE, VR-12 physical component, ASES, and WORC over 1 year MCID achieved at 1 year: SANE: 84,3% (161/191); VR-12 mental: 40,3% (77/191); VR-12 physical: 78,5% (150/191); ASES: 90,5% (86/95); WORC: 87,2% (116/133)
Thon SG, 2019 [47]	Overall final ASES score: 82,87 ± 16.68 (range: 53,33-100) for all patients No significant difference in ASES score at 5 years between large and massive tears final scores (p = 0,92)
	Partial-thickness
Bokor DJ, 2016 [37] 2019 [38]	Significant improvements in CMS and ASES pain scores (p ≤ 0,001) Persistent significant improvement in CMS and ASES during the 5-year FU period with no significant changes compared to the 2-year results
Bushnell BD, 2021[39]	Rate MCID met at 1 year: 93,1% for ASES; 91,6% for SANE; 33,9% for VR-12 MCS; 80,2% for VR-12 PCS; and 93,3% for WORC
Camacho Chacón JA, 2022 [42]	Significantly improved VAS, ASES and CMS score at 6 months and 1 year
McIntyre LF, 2019 [43]	Significant improvement in VAS, SANE, VR12 physical component, ASES, and WORC over 12 months FU (p < 0,05) MCID for VAS pain and ASES scores met by 84% and 83% of patients, respectively
Schlegel TF, 2018 [45] 2021 [46]	CMS scores significantly lower for intermediate-grade tears than high-grade at 3 months (51,5 vs. 73,7; p =0,0231) and 2 years (83,3 vs. 93,8; p = 0,0037), not at 1 year (82,2 vs.85,6; p = 0,3748) Intermediate-grade: 100 % met the MCID for both ASES and CMS at 2 years High-grade: MCID for ASES and CMS was met by 79,0% and 94,4% at 2 years, respectively

PROMs patient-reported outcome measures, FU follow-up, CMS Constant-Murley score, ASES American Shoulder and Elbow Surgeons score, VAS visual analogue scale, SANE single-assessment numeric evaluation, VR-12 Veterans RAND 12 Item Health Survey, WORC Western Ontario Rotator Cuff Index.

difference in clinical outcomes and in return to work with or without the use of Regeneten, Camacho et al. reported significantly higher MCID for clinical outcomes and a significantly faster return to work after Regeneten augmentation compared to classic repair[33,35]. Bushnell and Schlegel reported a mean time until return to work of 33 days and 54 days , respectively[39,46].

Radiological outcomes

MRI was used as the golden standard for diagnosis and follow-up after treatment in all articles reporting radiological outcomes (Table IV). Thon et al. also used ultrasound for postoperative assessment at 3 and 24 months[47]. Camacho et al. reported radiological outcomes without distinguishing between PT and FT tears[42]. All studies analysing Regeneten use in FT as well as PT tears reported increased tendon thickness from 6 months onwards, with MRI signals indicating implant integrating into native tendon and becoming indistinguishable from it. Bokor et al. reported slight decrease in tendon thickness between 12 and 24 months in FT tears and between 2 and 5 years in PT tears, after a significant increase initially in the first 12 months. In both studies, there was still a significant increase in tendon thickness compared to baseline[36,38].

Retear rate

The findings are presented in Table I. Only one study clearly described the use of the Sugaya classification to determine retears: images were considered as retears if classified as grade 4-5 according to this classification[35]. The implant showed retear rates ranging from 0% to 18% after 5 years for PT tears and from 0% to 35% after 2 years for FT tears. A significantly increased retear rate for large tears compared to medium tears was found, with most retears occurring within the first 3 months[40,41]. Similar to the clinical outcomes, there was a difference in retear rates between the 2 RCTs. The RCT with small to medium tears reported no retears (0 %), whereas the RCT with medium to large tears reported a retear rate of 8.33%, which was still significantly lower than that of the control group[33,35]. Factors such as rehabilitation compliance and the type of repair influenced outcomes[42-46].

Complications

Complications related to the implant and to the procedure are summarized in Table I. Among those related to the implant, the most commonly reported were infections, with both deep and superficial infections appearing multiple times[35,41,43, 44]. Other complications related to the implant, such as bursitis and intra-operative shoulder swelling appeared less frequently. The additional complications associated with implant use seem to be quite manageable. In terms of complications related to the procedure itself, adhesive capsulitis or postoperative stiffness was frequently noted across several studies[37,38,43,44]. Furthermore, Thon et al. reported a notably high incidence of postoperative scapular dyskinesia, affecting 35% of cases[47]. Two studies reported no complications[36,39].

Economic evaluation

Two studies assessed the economic benefit of using Regeneten implants in conjunction with conventional rotator cuff repair compared to conventional repair alone[48,49]. In the study conducted in the United States, the addition of Regeneten to conventional rotator cuff repair led to an additional cost of $232 468 per 100 patients treated annually and resulted in 18 more healed rotator cuff tears. The analysis showed an incremental cost-effectiveness ratio (ICER) of $13 061 per healed rotator cuff tear (RCT). Including the impact on return to work, Regeneten addition to conventional RCR proved to be cost-effective compared to conventional RCR alone, saving $469 017 per 100 treated patients with FT RCT, with cost-effectiveness improving with increasing size of tear[48]. Rognoni et al. adapted the analytic model of this study to perform a separate analysis in Italy of the combination of Regeneten with standard care versus standard care. This analysis showed an ICER of €17 857 per healed tear when using Regeneten. From the societal perspective, savings of €4918 per healed tear were shown when the bioinductive implant was used[49].

DISCUSSION

Despite major advances made over the last decades, retear has remained a main issue after rotator cuff repair. Augmentation of rotator cuff repair has previously been associated with lower retear rates[50]. The primary aim of our review was to assess the effectiveness of RCR enhanced with Regeneten used as a stand-alone repair or repair augmentation. Use of the implant was associated with retear rates of 0% up to 18% in PT tears and 0% up to 35% in FT tears, compared to retear rates ranging from 3,3% to 50% reported after conventional repair[10,11]. One of the two included RCTs showed no retears in either

Table IV. — Summary of radiological outcomes.

Study	Radiological outcomes
	Full-thickness
Camacho Chacón JA, 2024 [33]	6 months: tendon thickness significantly greater in the BCI group throughout FU 12 months: 100% tendon gap fill-in for all 30 patients (100%) in the BCI group, sustained at 24 months postoperatively
Ruiz Ibán M, 2024 [35]	12 months: structural continuity of the repaired tendon better in the implant group (p = 0,030)
Bokor DJ, 2015 [36]	6 months: significant (p = 0,01) increase in tendon thickness, averaging 2 mm of newly formed tissue, integrating well into the underlying tendon 24 months: neo-tendon becoming indistinguishable from native tendon on MRI
Bushnell BD, 2021[40] 2022[41]	24 months: mean total thickness of the supraspinatus tendon increased by 12,5% (p = 0,031) & by 17,1% (p =0,127) for medium & large tears respectively No visible boundaries identified between implant & tendon for any patient at 24 months
Thon SG, 2019 [47]	MRI at 13 months: mean thickness was 5,13 mm for all intact tendons US at 24 months: mean thickness of tendon was 7,72 mm (compared to 6,29 at 3 months)
	Partial-thickness
Bokor DJ, 2016 [37] 2019 [38]	Significant increase in mean tendon thickness: Preoperative: 4,28 ± 0,32 mm 5 years post-surgery: 5,16 ± 0,27 mm (p = 0,0012 compared to 2-year thickness)
Schlegel TF, 2018 [45] 2021 [46]	24 months: at least 50% fill-in of the defect was achieved in: 90,9% of intermediate-grade tears and 84,2% of high-grade tears. Mean thickness increased by: 1,2 mm (p = 0,012) in intermediate-grade tears; 1,8 mm (P = 0,003) in high-grade tears. No statistically significant difference in mean tendon thickness from 1 to 2 years. Boundary between the implant and the supraspinatus tendon no longer visible in any available patients at 1 & 2 years.
	Full- and partial-thickness
Camacho Chacón JA, 2022 [42]	6 months: significant increase (p = 0,001) in new tissue induction, with an average increase in tendon thickness of 1,84 mm. MRI signal of the neotendon indistinguishable from the underlying tendon at 6 months & unmodified at 12 months. Filing of the defects for all patients: 27 complete filling & 3 partial filling greater than 50%.

BCI bio-inductive collagen implant, FU follow-up, US ultrasound.

the Regeneten group or the control group, possibly because only FT tears smaller than 2.5 cm with an intact rotator cable were included[33]. The second RCT, which included medium to large FT tears, showed a lower retear rate for Regeneten augmentation compared to classic RC repair[35]. The retear rate for Regeneten seems to be lower compared to conventional repair, with lower rates for smaller FT tears and lower for PT than FT tears. More RCTs are needed to gain a better understanding of the retear rate after Regeneten use.

Statistically significant and clinically relevant post-operative improvements in clinical outcomes and PROM's after Regeneten implantation compared to baseline were achieved in FT as well as PT tears, whether used as a stand-alone repair or as an augmentation. However, postoperative MCID achievement rates for clinical outcomes and PROM's after Regeneten use seem to be in similar ranges compared to traditional RCR[51]. In some studies, Regeneten use was associated with faster recovery and return to work, with a mean time duration of return to work ranging from 33 to 54 days compared to 191 days after classic RCR reported in a level I meta-analysis[33,43,44,52].It needs to be noted that in one of the 2 included RCT's no significant improvement in clinical outcomes and return to work was found, compared to classic RC repair, even though the retear rate was significantly lower after Regeneten use[35]. This difference in outcomes could be explained by the different size of the FT tears: small to medium in Camacho's study and medium to large in Ruiz Ibán's study[33,35]. Based on this, it can currently be inferred that the benefit in terms of clinical outcomes may be more pronounced in smaller FT tears.

MRI-based evaluation of RC tendons showed significantly increased thickness and improved structural continuity of the repaired tendon when using the Regeneten implant compared to baseline and to classic RC repair. Induction of new tissue could be observed after 6 months and was indistinguishable

from the underlying tendon by 12 months[42,45,46]. It can be concluded that the implant seems effective in the short term; however, the long-term impact remains unclear due to the limited follow-up period of 24 months. An extended radiographic follow-up could be beneficial in evaluating the final outcome.

Tendon biopsies taken 6 months after Regeneten implantation showed fibrous connective tissue with highly organized, parallel collagen bundles[33,42]. On histological examination the newly formed tissue could not be differentiated from the native tissue, and no signs of inflammation, scarring, foreign body reactions or traces of the implant in the samples were noticed[33,42]. This is in alignment with the findings of Van Kampen et al., who carried out a study on sheep using highly-purified, type I collagen from bovine tendons, similar to Regeneten. This also resulted in well-integrated tissue comprised of fibroblasts and regularly-oriented collagen fibers at 26 weeks post-implantation[53].

Infections and adhesive capsulitis were the most common complications after Regeneten use. Brislin et al. reported that shoulder stiffness was also the most common complications after classic RCR, while infections were less common after classic RCR[54]. It can be concluded that infections are more frequent after implant use, while stiffness is not more common compared to traditional RCR. The overall complication rate for Regeneten-augmented RCR was 15.5% for full-thickness and 16,2% for partial-thickness tears, compared to 7-15,8% and 2,5-11,9%, respectively, in classic RCR[55]. A rare complication in response to orthopaedic implants is the formation of rice bodies. These structures are composed of fibrin at different stages of organization, and are seen as a nonspecific response to chronic synovial inflammation[56]. Two case reports of rice body formation after Regeneten implantation have been published up to present[57,58]. Both articles reported a subacromial-subdeltoid bursitis, with rice bodies formation, presenting with not recovering range of motion (ROM) and/or persistent pain during follow-up. Barad et al. hypothesized that this was due to the breakdown of the polylactic acid staples used to secure the implant[58]. However, Liu et al. noticed the resorption period of these staples does not seem to align with the timing of rice body formation, suggesting insufficient evidence to support a direct causal link[59]. Although this complication is rare, ongoing pain, swelling, or reduced ROM lasting several months after rotator cuff repair with a collagen implant may justify an early MRI scan to assess for any underlying issues[57].

A major concern about adopting Regeneten as a standard of care is the cost of the implant. Rognoni et al. reported that the mean price for the implant was €3484 in Italy[47]. McIntyre and Rognoni both found that the use of Regeneten for rotator cuff tear repair might be cost-saving compared to conventional surgery, considering the faster return to work[48,49]. McIntyre also noticed that cost-effectiveness increased with the size of the tear, showing the greatest benefit in massive tears compared to large tears, as well as in patients who had a higher risk of re-tearing[48]. It indeed seems plausible that, given the lower retear rate, faster recovery and return to work, Regeneten is cost-effective for certain patients despite the high initial cost. Ultimately, it will be essential to determine the most appropriate use of this implant given its cost, by identifying which patients will gain the most benefit and which ones may not.

Our study is subject to several limitations. First, only two randomized controlled trials were available, with the rest being mainly case series classified as level IV evidence. One of these RCTs reported a retear rate of 0% after 24 months in both the Regeneten and control groups, which does not seem to align with the existing literature and should therefore be interpreted with caution[33]. The lack of a control group in the case series makes it difficult to evaluate the added value of Regeneten in rotator cuff tear repair, compared to classic repair. In eight of these case series patient were not enrolled consecutively, increasing the risk of introducing selection bias. One of these studies was retrospective, which further exacerbates the issue of bias. Seven included articles also had a small sample size, with less than 50 patients recruited. At the time of screening of articles, at least 9 randomized studies were ongoing for Regeneten, but were excluded due to insufficient follow-up. Second, no statistical analysis was performed due to the clinical heterogeneity of the included studies in terms of extent of tear, implant use, follow-up duration and reported outcomes. A third limitation is that the identification and screening of articles were both performed by only one researcher, which increases the risk of missing relevant studies or incorrectly screening articles. However, the availability of two supervising researchers to address doubts and reach consensus helped ensure the review's accuracy and reliability. Finally, only one of the included articles had no conflict of interest, while all other studies were either funded by Smith & Nephew or written by authors who had received financial remuneration from the company.

CONCLUSION

Current evidence shows that the use of Regeneten for the repair of rotator cuff tears of all sizes and chronicity is associated with lower retear rates and improved clinical outcomes in some studies. However, the clinical outcomes remain within the same range as those seen after traditional rotator cuff repair. On MRI, enhanced tendon thickness and structural integrity were observed. Despite a low overall complication rate, infections and adhesive capsulitis were the most frequently reported issues among patients. Considering the faster return to work, Regeneten use might be cost saving compared to conventional surgery in certain cases. More randomized controlled studies are needed to confirm these findings and to determine the appropriate use of this implant.

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