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CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

Chitosan-Based Scaffolds During Orthopedic Surgery in Adults: Clinical Effectiveness, Cost-Effectiveness, and Guidelines

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Research Questions

1. What is the clinical effectiveness of using chitosan-based scaffolds during orthopedic surgery in patients with cartilage loss?
2. What is the cost-effectiveness of using chitosan-based scaffolds during orthopedic surgery in patients with cartilage loss?
3. What are the evidence-based guidelines regarding the use of chitosan-based scaffolds during orthopedic surgery in patients with cartilage loss?

Key Findings

One systematic review, two randomized controlled trials, and one non-randomized study were identified regarding the clinical effectiveness of using chitosan-based scaffolds during orthopedic surgery in patients with cartilage loss in the knee. One economic evaluation was identified regarding the cost-effectiveness of using chitosan-based scaffolds during orthopedic surgery in patients with cartilage loss in the knee. No relevant evidence-based guidelines were identified regarding the use of chitosan-based scaffolds during orthopedic surgery in patients with cartilage loss in the knees or hips.

Methods

A limited literature search was conducted by an information specialist on key resources including Medline via OVID, Scopus, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were chitosan and cartilage or orthopedics. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2015 and January 9, 2020. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients with cartilage loss Subgroups: • Patients with cartilage loss in their knees • Patients with cartilage loss in their hips
Intervention	Orthopedic surgery performed with chitosan-based scaffolds (e.g., microfractures combined with chitosan-based scaffolds)
Comparator	Orthopedic surgery performed without chitosan-based scaffolds (e.g., microfractures alone)
Outcomes	Q1: Clinical effectiveness (e.g., pain [e.g., measures using pain scales], degree of lesion filling, tissue repair quality, failure rate, healing rate, quality of life, patient satisfaction, safety [e.g., rates of adverse events]) Q2: Cost-effectiveness Q3: Guidelines
Study Designs	Health technology assessments, systematic reviews, randomized control trials, non-randomized studies, economic evaluations, evidence-based guidelines

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

One systematic review[1], two randomized controlled trials[2,3], and one non-randomized study[4] were identified regarding the clinical effectiveness of using chitosan-based scaffolds during orthopedic surgery in patients with cartilage loss in the knee. One economic evaluation[5] was identified regarding the cost-effectiveness of using chitosan-based scaffolds during orthopedic surgery in patients with cartilage loss in the knee. No relevant health technology assessments, or evidence-based guidelines were identified.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

One systematic review,[1] two randomized controlled trials,[2,3] and one non-randomized study[4] were identified regarding the clinical effectiveness of chitosan-based scaffolds for patients with cartilage loss in the knee. The systematic review[1] assessed the clinical effectiveness of various surgical treatments for cartilage defects of the knee. One primary study that compared BST-CarGel to microfracture alone was identified in the review; However, the findings of this study were not described in the abstract.[1] The authors of the systematic review concluded that no single treatment could be recommended for the treatment of knee cartilage defects.[1] In the first randomized controlled trial,[2] safety and efficacy outcomes of BST-CarGel treatment compared to microfracture alone in the knee were assessed 12 months post-treatment. BST-CarGel treatment resulted in better filling, integration, tissue appearance and improved structural and cellular characteristics of repair tissue in the knee compared with microfracture alone.[2] The authors concluded that these findings support previously reported results by quantitative magnetic resonance imaging (MRI).[2] In the second randomized controlled trial,[3] participants with lesions on the femoral

condyles were randomized to receive BST-CarGel treatment or microfracture alone, and 12-weeks of rehabilitation. Participants treated with BST-CarGel demonstrated significant improvements for lesion filling and repair tissue relaxation times. Both treatment groups experienced significant improvements in clinical benefit scores from baseline, although the between-group differences were non-significant.[3] Overall, the authors concluded that BST-CarGel treatment was an effective cartilage repair treatment which resulted in superior repair tissue quantity and quality five years post-treatment over microfracture alone.[3] The non-randomized study[4] assessed clinical and radiographic outcomes of chitosan-glycerol/blood implant (i.e., chitosan-based scaffolds) versus hyaluronic acid-based cell-free scaffold in patients with focal osteochondral lesions of the knee joint in short-term follow-up. The authors reported no significant differences in clinical outcomes between the two groups, with the exception of better outcomes observed in larger lesion sizes in the chitosan-based scaffold group.[4] Additionally, MRI observation of cartilage repair tissue (MOCART) found no differences in tissue repair between the two groups.[4] The authors concluded that chitosan-based scaffolds are an effective choice in patients with larger lesion sizes.[4]

One economic evaluation[5] regarding the cost-effectiveness of orthopedic surgery performed with chitosan-based scaffolds in patients with cartilage loss in the knee was identified. The study evaluated the economic value of bioscaffolds versus microfracture alone in knee cartilage repair from the German societal perspective.[5] In a group of patients with variable lesion sizes, the authors found that bioscaffolds yielded a positive return on investment in year four, and that cost savings were greatest in patients with larger lesions.[5] The authors concluded that chitosan-beta glycerolphosphate bioscaffolds may be cost-effective for patients with knee cartilage injury due to lower risk of undesirable clinical events, which was defined as pain management, surgery and total knee replacement.[5]

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

Patients with Cartilage Loss in the Knees

1. Devitt BM, Bell SW, Webster KE, Feller JA, Whitehead TS. Surgical treatments of cartilage defects of the knee: systematic review of randomised controlled trials. *Knee*. 2017;24(3):508-517.
PubMed: PM28189406

Randomized Controlled Trials

Patients with Cartilage Loss in the Knees

2. Methot S, Changoor A, Tran-Khanh N, et al. Osteochondral biopsy analysis demonstrates that BST-CarGel treatment improves structural and cellular characteristics of cartilage repair tissue compared with microfracture. *Cartilage*. 2016;7(1):16-28.
PubMed: PM26958314

3. Shive MS, Stanish WD, McCormack R, et al. BST-CarGel treatment maintains cartilage repair superiority over microfracture at 5 years in a multicenter randomized controlled trial. *Cartilage*. 2015;6(2):62-72.
PubMed: PM26069709

Non-Randomized Studies

Patients with Cartilage Loss in the Knees

4. Sofu H, Camurcu Y, Ucpunar H, Ozcan S, Yurten H, Sahin V. Clinical and radiographic outcomes of chitosan-glycerol phosphate/blood implant are similar with hyaluronic acid-based cell-free scaffold in the treatment of focal osteochondral lesions of the knee joint. *Knee Surg Sports Traumatol Arthrosc*. 2019;27(3):773-781.
PubMed: PM30069652

Economic Evaluations

5. Frappier J. Economic evaluation of BST-Cargel as an adjunct to microfracture versus microfracture alone in knee cartilage surgery. *Value In Health*. 2015;18(3):A4.
https://www.valueinhealthjournal.com/article/S1098-3015(15)00079-0/fulltext. Accessed 2020 Jan 22.

Guidelines and Recommendations

No literature identified.

Appendix — Further Information

Previous CADTH Reports

6. Emerging technology list — BST-CarGel™ for cartilage repair. Ottawa (ON): Canadian Coordinating Office for Health Technology Assessment; 2004; https://www.cadth.ca/emerging-technology-list-bst-cargeltm-cartilage-repair. Accessed 2020 Jan 22.

Non-Randomized Studies – No Comparator

Patients with Cartilage Loss in the Knees

7. Steinwachs M, Cavalcanti N, Mauuva Venkatesh Reddy S, Werner C, Tschopp D, Choudur HN. Arthroscopic and open treatment of cartilage lesions with BST-CARGEL scaffold and microfracture: a cohort study of consecutive patients. *Knee*. 2019;26(1):174-184.
PubMed: PM30579660

Case Series

Patients with Cartilage Loss in the Hips

8. Rhee C, Amar E, Glazebrook M, Coday C, Wong IH. Safety profile and short-term outcomes of BST-CarGel as an adjunct to microfracture for the treatment of chondral lesions of the hip. *Orthop J Sports Med*. 2018;6(8):2325967118789871.
PubMed: PM30116764

9. Tahoun MF, Tey M, Mas J, Abd-Elsattar Eid T, Monllau JC. Arthroscopic repair of acetabular cartilage lesions by chitosan-based scaffold: clinical evaluation at minimum 2 years follow-up. *Arthroscopy*. 2018;34(10):2821-2828.
PubMed: PM30195954

10. Rhee C, Amar E, Wong I. Arthroscopic treatment of acetabular chondral defect using Bst-Cargel. *J Hip Preservation Surgery.* 2016;3(Supp 1).
https://academic.oup.com/jhps/article/3/suppl_1/hnw030.044/2352966. Accessed 2020 Jan 22.