

Unicompartmental interpositional implant for osteoarthritis of the knee

A systematic review

By

WorkSafeBC Evidence-Based Practice Group

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About this report

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About the Evidence-Based Practice Group

The Evidence-Based Practice Group was established to address the many medical and policy issues that WorkSafeBC officers deal with on a regular basis. Members apply established techniques of critical appraisal and evidence-based review of topics solicited from both WorkSafeBC staff and other interested parties such as surgeons, medical specialists, and rehabilitation providers.

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Background

Osteoarthritis (OA) of the knee is the result of progressive degeneration of the meniscus and articular cartilage of the joint, which leads to the exposure of the bone surface.^(679,685) This degeneration can affect any or all of the three compartments of the knee joint (medial, lateral, or patello-femoral). Knee ligaments may also be compromised, leading to instability of the knee. With regard to compartment involvement, it is estimated that about one-third of patients have OA predominantly in only one compartment of the knee – hence the term unicompartmental OA of the knee. Unicompartmental OA usually occurs in the patello-femoral compartment (\pm 69% of patients with unicompartmental OA). However, nearly one-third of patients may have OA in the medial compartment only.^(679,685)

OA of the knee causes pain, stiffness, swelling and difficulty in walking. OA, which is usually a chronic disease condition, may require treatment depending on its level of severity or disease stage.⁽⁶⁸⁵⁻⁶⁸⁷⁾ Conservative treatments include medication to relieve pain and inflammation, physiotherapy and/or exercise, corticosteroid injection, and viscosupplementation. If these therapies do not adequately relieve the symptoms and functional impairment, patients may be offered surgical options. Surgical options to treat knee OA include knee arthroscopy and lavage with/without debridement, microfracture, osteotomy, unicompartmental arthroplasty, and total knee arthroplasty.^(366,555,591,682,684) In 2002, Moseley et al.⁽⁶⁸⁸⁾ conducted a randomized controlled trial showing that placebo surgery was as effective as arthroscopic lavage with/without debridement in treating knee OA. Microfracture is advocated for younger patients but is not indicated for patients with malalignment.⁽⁵⁹¹⁾ Proximal tibial osteotomy corrects malalignment (but the long term results have not been encouraging), while unicompartmental arthroplasty requires bone resection that may compromise needed future treatment (c.q. total knee arthroplasty) and requires subsequent activity modification.⁽⁵⁹¹⁾ Total knee arthroplasty is typically not recommended for patients who are younger than 55 years old (those most likely to require subsequent revision surgery).

Interpositional implants were developed in order to manage pain and increase function in a way that preserves bone and delays the need for a knee replacement.^(555,682) Both biologic and metal interpositional implant/arthroplasty procedures are currently available for the treatment of unicompartmental OA. In biologic interpositional arthroplasty, an allograft meniscus is employed in the transplantation.⁽⁶⁸²⁾ Metal interpositional arthroplasty procedures were first developed in the 1950s by MacIntosh and McKeever.⁽⁵⁷⁴⁾ This procedure was practically abandoned when joint replacement arthroplasty with methymethacrylate was introduced. However, metal interpositional arthroplasty has recently seen a comeback with the development of a prosthetic device marketed as UniSpacer.^(366,574,684) Based on 510(k) Exemption, the US FDA approved UniSpacer in 2000 with the purpose of restoring alignment of the knee by functioning in the same way an osteotomy might.⁽⁵⁵⁵⁾ A second interpositional device, the iForma, also came to the market recently through a 510(k) exemption. As opposed to the “mass produced” UniSpacer, which is only available in 24 sizes, iForma is custom manufactured, using MRI scans, to be fitted specifically for an individual

patient.⁽⁶⁸²⁾ These new devices are thought to restore alignment and stability by replacing missing articular and meniscal cartilage with a metallic implant. UniSpacer can be thought of as a mobile McKeever or MacIntosh implant. Instead of an attempt at fixation to the tibial plateau via a keel or roughened undersurface, UniSpacer is designed to translate freely on the tibial plateau as determined by the conforming articulation of its top surface with the femoral condyle. The insertion of the implant does not require any bone resection or any mechanical fixation to the tibial plateau for proper function.⁽⁶⁸⁴⁾ The iForma implant is a self-fixating version of a metallic hemiarthroplasty as previously described by MacIntosh and McKeever.⁽⁴²³⁾ By using three dimensional sizing software, an individual medial or lateral interpositional implant is generated based on the MRI data of the affected knee joint. The generated device is then implanted using a minimally invasive technique with a 5 cm incision. iForma is characterized by a highly constraining undersurface that exactly mirrors the tibial plateau with resultant self fixation on the tibia. The implant's individual adaptation to each patient's respective surface geometry is thought to provide a functionally stable fit.⁽⁴²³⁾

In October 2009, the Evidence-Based Practice Group (EBPG) was asked to review the evidence on the efficacy/effectiveness of OrthoGlide, another type of interpositional implant, in treating an injured worker diagnosed with medial compartment OA. Despite an extensive and systematic literature search, the EBPG was unable to find any published studies to support/refute the efficacy/effectiveness of OrthoGlide at that time. A rapid systematic review on OrthoGlide is attached (Appendix 1). In late April 2010, the issue of provision of interpositional arthroplasty (besides OrthoGlide) to treat the same injured worker re-emerged and the EBPG was asked to review the evidence on the efficacy/effectiveness of interpositional implants to treat medial compartment OA. As such, the objective of this systematic review is to identify, critically appraise, and summarize the evidence on the efficacy/effectiveness of interpositional implants for lateral as well as medial compartment OA.

Methods

The orthopaedist proposing interpositional arthroplasty for this injured worker informed the EBPG that Dr. Richard Scott from Harvard has published a number of papers regarding interpositional arthroplasty. However, the orthopaedist did not provide any information regarding which implant (OrthoGlide, UniSpacer or iForma) he is proposing to use (*subsequent information received on May 20, 2010 showed that the device would be OrthoGlide*). The first systematic literature search was conducted in order to identify studies, especially on interpositional knee implants, published by Dr. Richard Scott of Harvard.

A systematic literature search to identify the name that Dr. Scott used in his published papers was conducted on April 28, 2010. The search was done on PubMed by employing the simple combination keywords of ((Scott (*as author*)) AND harvard (*as keyword*)). This search yielded 201 citations.⁽¹⁻²⁰¹⁾ Upon examination of the titles and abstracts of these citations, we identified that Dr. Richard Scott of Harvard uses “Scott RD” as his name in published studies. The results of this search were then employed in the second search. *Please note that references 1-201, to identify Dr. Richard Scott’s name, are provided for your information only as it does not have any direct effect on the outcome of this systematic review.*

The second search was conducted in order to identify Dr. Scott’s published studies on interpositional implants. Systematic literature searching was undertaken on April 30, 2010 on commercial databases including BIOSIS Previews, EMBASE, Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE and Ovid MEDLINE Daily Update. These databases are available through the OvidSP interface. Searching employed the combination keywords of (((scott rd).au) AND ((interpositional OR inter-positional) AND arthroplasty)). Two articles⁽²⁰²⁻²⁰³⁾ were identified but upon examination of their titles and abstracts, there was no evidence of relevancy to the objective of this review; as such, we did not retrieve these articles in full (Appendix 2).

A third search was conducted in order to identify any published studies on interpositional implants for the knee. Systematic literature searching was again undertaken on April 30, 2010 on commercial databases including the Cochrane Database of Systematic Reviews, ACP Journal Club, the York University-UK Database of Abstracts of Reviews of Effects, Cochrane Controlled Trial Registry, York University-UK Health Technology Assessment database, York University- UK NHS Economic Evaluation database, BIOSIS Previews, EMBASE, Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE and Ovid MEDLINE Daily Update. These databases are available through the OvidSP interface. *It should be noted that we re-did the literature search for OrthoGlide as well.*

Searching employed the combination keywords of: ((orthoglide OR ortho-glide OR ortho glide OR unicondylar interpositional spacer OR knee interpositional mini-repair system OR knee interpositional mini repair system OR kimrs) OR ((interpositional OR inter-positional) AND

(device* or implant* or arthroplasty)) OR ((mckeever OR macintosh) AND ((interpositional OR inter-positional) AND (device* OR implant* OR arthroplasty))) OR ((unicompartmental AND ((interpositional OR inter-positional) AND (device* OR implant* OR arthroplasty))) OR (conformis OR unispacer OR zimmer)) **AND** (knee OR knee joint). We then limited these searches to studies conducted in humans. Four hundred seventy-five articles⁽²⁰⁴⁻⁶⁷⁸⁾ were identified.

Searching was also conducted on the websites of the US Agency for Healthcare Research and Quality (www.ahrq.gov) as well as the UK National Institute for Health and Clinical Excellence (www.nice.org.uk) in order to identify additional published systematic reviews conducted by these organizations that may not have been identified through previous searching of the York University-UK Health Technology Assessment database. Two systematic reviews, on MRI-based design of interpositional implants⁽⁶⁸⁶⁾ and treatment of OA of the knee,⁽⁶⁸⁷⁾ were identified.

Upon examination of the titles and abstracts of these 477 articles,^(204-678,686,687) eighteen articles^(234,246,309,319,337,355,365,366,367,373,423,509,554,555,574,591,686,687) were considered to be relevant and were retrieved in full for further appraisal.

Manual searching of the references of the fully retrieved articles^(234,246,309,319,337,355,365,366,367,373,423,509,554,555,574,591,686,687) were also conducted. This searching further identified seven articles⁽⁶⁷⁹⁻⁶⁸⁵⁾ which were thought to be relevant and were retrieved in full. As such, overall, twenty-five^(234,246,309,319,337,355,365,366,367,373,423,509,554,555,574,591,679-687) articles were retrieved in full and appraised further.

Of these twenty-five articles^(234,246,309,319,337,355,365,366,367,373,423,509,554,555,574,591,679-687), seventeen were excluded^(246,309,319,337,355,366,373,509,555,574,679,681-685,687) due to irrelevancy to the objective of this review (such as those on total knee arthroplasty), duplication of primary data published elsewhere, being expert reviews, or consisting of primary data which was generated from computer simulation. As such, overall, eight studies^(234,365,367,423,554,591,680,686) are presented further below.

Results

As with our prior searching on October 22, 2009, no published studies on OrthoGlide were identified. As such, as of April 30, 2010, there was still no published evidence on the efficacy/effectiveness of OrthoGlide in treating medial compartment knee OA.

In an attempt to investigate whether the self-centering property of UniSpacer could provide alignment correction in patients with medial compartment OA, Clarius et al.⁽⁶⁸⁰⁾ studied the radiographs of 18 patients (19 legs) before and after their implantation with UniSpacer. This small case series (Level of evidence 5. Appendix 3) showed that during the first post-operative year, leg axis correction of an average of $4.7 \pm 1.9^\circ$ valgus change was achieved. During the five-year follow up period, 21% of UniSpacer implants were converted to unilateral (UKA) or total knee arthroplasty (TKA) due to persistent pain. The mean (and SD) for time to revision to UKA/TKA was 23.8 ± 18.0 months. The authors also provided data on the mean (*presumably, and without SD or SE*) Lysholm score and American Knee Society (AKS) Knee and Function scores at pre-operative baseline and one, two, and five years post-operative timepoints. *Even though there was improvement with regard to Lysholm, AKS Knee, and AKS Function scores, given the information provided, it is not clear whether these improvements were statistically or clinically significant. The authors provided minimal information on methods and data in this paper.*

Richard Hallock, a chief proponent of UniSpacer,⁽⁵⁷⁴⁾ reported what were most likely the first outcomes on the application of UniSpacer to treat isolated medial compartment knee OA.⁽³⁶⁷⁾ In this case series (Level of evidence 5. Appendix 3), Hallock and Fell reported the implantation of 71 UniSpacers in 67 patients with medial compartment knee OA. After one year, 66 knees (63 patients) still had their implants. At one year post-operative, the authors noted that there was 169% improvement in the mean AKS Knee score (from a preoperative level of 29 to 78 points); the AKS Function score improved 31% (from 55 points preoperatively to 72 points), and the Lyshold score improved by 88% (from a mean of 41 points to 77 points). *It should be noted that it is not clear whether these improvements were statistically or clinically significantly different since the authors did not provide any information on this issue and it is not possible for us to compute it given the unavailability of data on its standard deviation. Further, many experts argue that AKS Knee and AKS Function scores between 70-79 points are considered 'fair'.⁽⁵⁹¹⁾* At the time of publication, the authors reported two years of follow up data on only 13 knees from 12 patients. This data will not be discussed further since the potential of bias in arriving at conclusions based on this small subset of data is significant. Within one year, ten patients (14%) underwent implant revision due to persistent pain or implant dislocation; a further five patients (7%) had their UniSpacer converted to TKA due to inadequate pain relief. As such, within one year, 21% of patients required surgical revision to their implants. *Besides the unavailability of controls or a comparison group, perhaps the biggest challenge in interpreting the data available from this case series is the fact that the authors did not provide any information at all on how they came to select these patients. Despite the inclusion and exclusion criteria provided by the authors, it is very difficult to exclude potential selection bias in the*

reporting of this case series.

In a more recent study, Hallock⁽³⁶⁵⁾ reported the outcomes of two groups of patients implanted with UniSpacer; Group 1 consisted of 79 knees and Group 2 consisted of 78 knees (Level of evidence 5. Appendix 3). Hallock compared the outcomes of these two, *undefined*, subsequent sets of patients with respect to their Lysholm score, AKS Knee score, AKS Function score, and patient satisfaction in a follow up period of between 15 and 48 months. During this follow up, Group 1 improved an average of 38 points in Lysholm, 49 points in AKS Knee score and 22 points in AKS Function score. Scores in Group 2 improved on average 25 points in Lysholm score, 40 points in AKS Knee score and 11 points in AKS Function score. The overall revision rate in Group 1 was 23% while in Group 2 it was 5%. *The author did not provide any information at all on how these patients were recruited and what differences existed, if any, between Group 1 and Group 2. Given the information provided in this paper, the claimed success of the procedure cannot truly be evaluated since selection bias cannot be ruled out in interpreting the outcomes.*

Bailie et al.⁽²³⁴⁾ reported the outcomes of a series of 18 consecutive patients, recruited between June 2003 and August 2004, treated with UniSpacer. In this small case series (Level of evidence 5. Appendix 3) Bailie et al. reported that, at the average follow up of 17 months, 17 patients (94%) had persistent pain within the first 3 to 6 months post-operation, 12 patients (67%) required co-intervention, and there were 8 (44%) implant failures. The authors stated their overall disappointment with the outcomes of this procedure. *Even though this study is also a case series, and hence without any comparisons, we appraised this study to be of good quality due to the fact that the authors stated how the patients were recruited (c.q. all patients during a certain period of time).*

In another small case series (Level of evidence 5. Appendix 3), Sisto and Mitchell⁽⁵⁹¹⁾ reported the outcomes of 34 patients (37 knees), recruited from April to November 2002, and treated with UniSpacer. Outcomes in this study were measured by employing AKS Knee and Function scores. Further, the authors categorized these scores into excellent (90 points), good (80 to 89 points), fair (70 to 79 points), or poor (< 70 points). *(It is not clear how the authors set the cut off points for these categories of AKS scores. Further, it is not clear whether these categories have been validated).* After a mean follow up of 26 months (range: 24 – 29 months), there were no excellent, 10 good, 15 fair, and 12 poor results on AKS Function score. Further, even though the mean post-operative AKS Knee and Function scores (72 points and 69 points, respectively) were better than the pre-operative scores (62 points and 60 points, respectively), these differences were not statistically significant. Of the 12 knees (32%) with poor results, 6 were due to dislocation of UniSpacer. All of these 12 knees (32%) with poor results required revision to TKA. Based on this result, the authors did not recommend the use of UniSpacer. *This small case series also did not provide any controls or adjustment of potential factors, such as age, height, sex, or occupation, potentially affecting the outcome of the surgery. However, this case series is also appraised to be somewhat better than other case series reported in this review since selection bias is minimized by reporting the recruitment*

period of the study participants.

Koeck et al.⁽⁴²³⁾ reported the only published study so far on ConforMIS iForma, an interpositional implant that is custom made according to knee MRI findings of the individual patient. The purpose of this study was to investigate whether this novel device was able to achieve appropriate leg axis correction. In this small case series (Level of evidence 5. Appendix 3), 27 patients were implanted with iForma: 23 medially and 4 laterally. (*It should be noted that due to its anatomical structure, iForma, unlike UniSpacer, can be used as a lateral compartment implant.*) At six weeks post-op the authors concluded that 23 implants (85%) achieved the objective of the operation (i.e. to correct leg axis to 0° and/or to a slight under-correction of up to 2°). *It should be noted that no other outcome measurements were presented in this case series. Further, it is unclear how leg axis correction had any effect on the level of pain, function, and quality of life of these patients.*

The UK National Institute for Health and Clinical Excellence (NICE) published a rapid systematic review⁽⁶⁸⁶⁾ (Level of evidence 1. Appendix 3) investigating the efficacy/effectiveness of magnetic resonance imaging-designed unicompartmental interpositional implants (*at present the only device investigated has been iForma*) to treat OA of the knee. This systematic review identified one published study (the one reported by Koeck et al.⁽⁴²³⁾) and incorporated two sets of unpublished data submitted by two orthopaedic consultants in the UK. The additional unpublished data from 84 and 60 patients only reported on the occurrence of revision, which was 5% and 7%, respectively. Based on this rapid systematic review, NICE issued clinical guidelines⁽⁶⁸⁸⁾ in September 2009 stating that current evidence on the safety and efficacy of individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for knee OA was inadequate in quality and quantity, and as such the procedure should be considered experimental.

In December 2008, the American Academy of Orthopaedic Surgeons (AAOS) published a clinical practice guideline on the treatment of OA of the knee (nonarthroplasty).⁽⁵⁵⁴⁾

With regard to interpositional implants, the organization suggested, based on the outcome of a study conducted by Sisto et al.⁽⁵⁹¹⁾ and the Australian Joint Replacement Registry,⁽⁶⁸⁵⁾ that free-floating (*at that time and at present only UniSpacer is said to be free floating*) interpositional devices not be used for patients with symptomatic unicompartmental OA of the knee.

Summary/Conclusions

- Repeat comprehensive literature searching on OrthoGlide did not identify any published primary studies on this topic. So far, the majority of published primary studies on unicompartmental interpositional implants to treat knee OA are on UniSpacer. There was also one published primary study on iForma, another device on the market.
- The primary studies identified were of low level (Level of evidence 5. Appendix 3) and low quality. Selection bias cannot be ruled out and its effect on the outcome of interest cannot be assessed regardless of the fact that the inclusion and exclusion criteria of patients were provided.
- At best, at present, these low level, low quality primary studies provide conflicting evidence on the efficacy of unicompartmental interpositional implants in treating knee OA as measured by Lysholm score and AKS Knee and Function scores.
- At present, the two evidence-based clinical practice guidelines identified in this systematic review do not recommend the regular application of unicompartmental interpositional implants to treat unicompartmental knee OA.

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Appendix 1

Rapid systematic review on the efficacy/effectiveness of OrthoGlide in treating medial compartment osteoarthritis of the knee.

From: Noertjojo, Kukul

Sent: Thursday, October 22, 2009 3:12 PM

Subject: RE: Ortho-glide

Dear All.

We have done a systematic review on this issue, please find the summary below.

Thank you.

Question: what is the evidence on the efficacy/effectiveness of ortho-glide (Advanced Bio-Surface) in treating osteoarthritis (OA) of the medial compartment of the knee

Methods:

- Systematic literature search was done on October 22, 2009.
- The search was done on commercial medical literature databases, including Cochrane Database of Systematic Review, ACP Journal Club, York University Database of Abstracts of Reviews of Effect, Cochrane Central Register of Control Trial, Cochrane Methodology Register, Health Technology Assessment, NHS Economic Evaluation Database, MEDLINE, MEDLINE Daily Update, EMBASE and BIOSIS Previews that are available through OVID SP interface.
- The searches were done by employing keywords of the devices as well as the clinical director of Advanced Bio-surfaces that was reported in the company's websites to present the report of the preliminary study in the November 10, 2007 American Academy of Rheumatology meeting. The keywords employed were as follows:
 1. orthoglide OR ortho-glide OR ortho glide OR unicondylar interpositional spacer OR knee interpositional mini-repair system OR knee interpositional mini repair system OR kimrs
 2. (arnold w) AND ((american college of rheumatology) OR (advanced bio-surfaces))
- Please note that unicondylar interpositional spacer and knee interpositional mini-repair system are similar devices have been approved by US FDA and was employed by Advance Bio-surfaces in applying orthoglide's 510K (in November 2, 2005).

Results:

- By employing search strategy no. 1 (above) EBPG was not able to identify any published literature. Search strategy number 2 yielded 1 published study (ref. 1) which is not relevant to our objective.
- Search on US FDA medical device database also failed to identify any relevant data as well
- Through internet search we were able to identify news story of Orthoglide (ref. 2). The abstract of the news was presented below, however, we strongly caution that to date there is no way for the EBPG to verify this data nor evidence that this data/news has gone through a peer review process prior to its publication
 - 92 patients were implanted at 6 approved sites in the United States. Fourteen (**15%**) of the enrolled patients have surpassed the one year implant follow up. The demographics of the study group include an average age of 60 years, 52% male / 48% female and WOMAC Pain scores which improve from 35 pre-operatively to 72 at 6 months and 74 at one year post-operative. Nine patients enrolled (10.2%) were converted to unicompartmental knee or total knee replacement.

- *The evidence provided in this news showed lack of control group as well as detailed characteristics of the patients and the outcomes (incl. the number that reached 6 and 12 months follow up) incl. its statistical significant differences, if any.*

Summary/Conclusion:

- Orthoglide, a medial knee implant developed by Advanced Bio-Surface, is indicated to treat moderate OA of the medial compartment of the knee
- To date, there was no published study to support/refute the efficacy/effectiveness of Orthoglide (and other medial knee compartment implant) in treating moderate medial compartment knee OA.

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2. ..Clinical data presented on Orthoglide medial knee implant. Downloaded from <http://www.medicalnewstoday.com/articles/87916.php> on September 23, 2009.

From: Noertjojo, Kukul

Sent: Wednesday, October 21, 2009 1:21 PM

Subject: RE: Ortho-glide

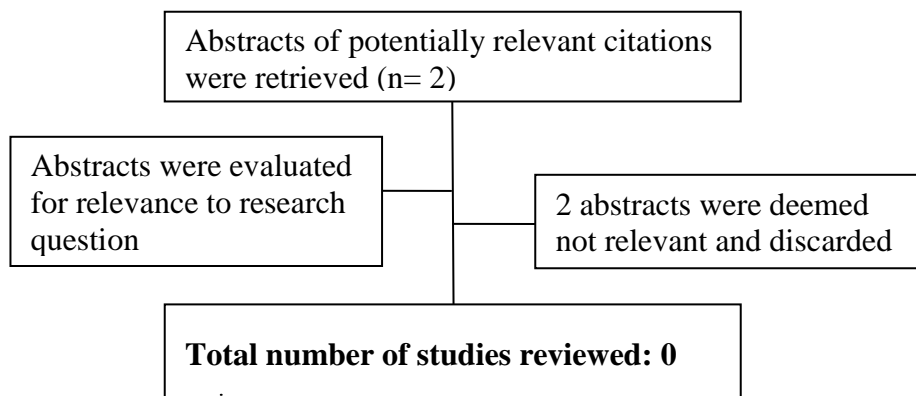
- We contacted Health Canada and received a reply that the device is registered with Health Canada (does not require any clinical evidence)
- We looked into the US FDA as well and we found that:
 - Orthoglide medial knee implant is a device made of Co-Cr-Mo alloy, is placed in the medial compartment of knee between the tibial plateau and femoral condyle
 - **it is intended to use in osteoarthritic knee in the treatment of moderate degeneration of the medial compartment of the knee (grade II-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss joint space) in the lateral and patellofemoral compartment**
 - the device was submitted for US FDA approval based on 510K approval of similarity with: 1. Sulzer Orthopedics Unicondylar Interpositional Spacer and 2. ITI Knee Interpositional Mini-repair system
 - the only study that they have done and submitted to US FDA were bench study and cadaveric study (for testing of the surgical instrument)
- We did a comprehensive literature search on orthoglide in September 2009 and did not find any published study on Orthoglide itself.

We did the US FDA search after we did the systematic literature search (because we did not find any published study) as such we haven't done the search on Sulzer and ITI devices. We will do it now.

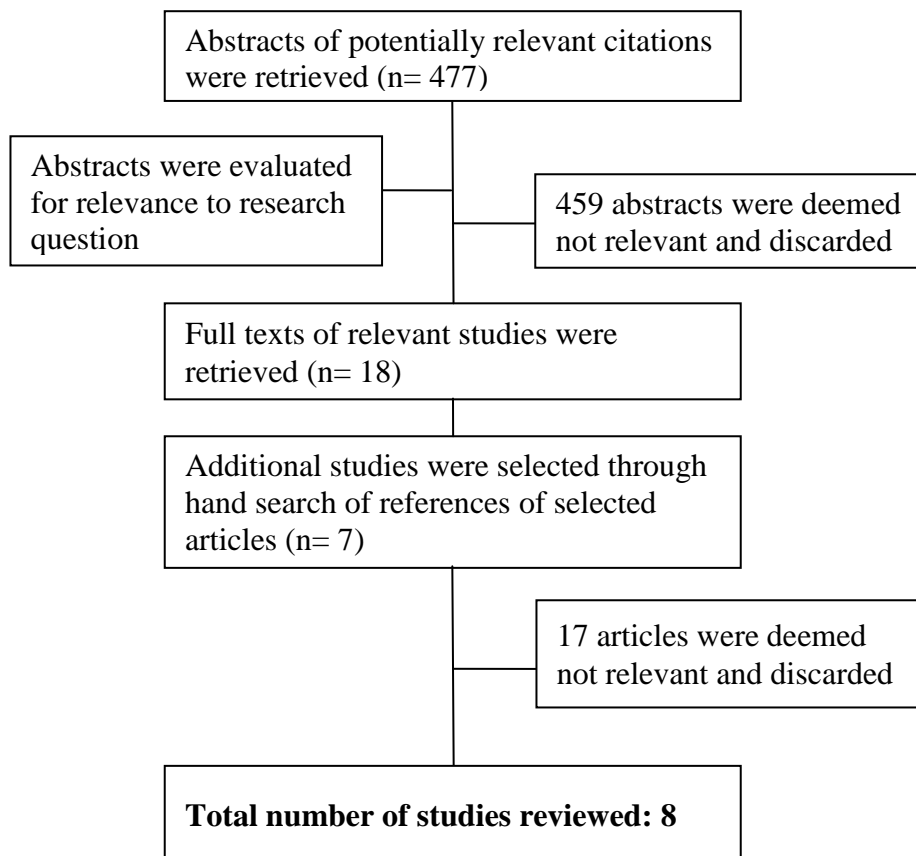
Appendix 2

Flow diagram (Study selection)

Second search



Third search



Appendix 3

WorkSafeBC Evidence-Based Practice Group levels of evidence (adapted from 1,2,3,4)

1	Evidence from at least 1 properly randomized controlled trial (RCT) or systematic review of RCTs.
2	Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.
3	Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

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