



TITLE: **Knee Joint Spacer (UniSpacer) System for Osteoarthritis of the Knee**

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KNEE JOINT SPACER (UNISPACER™) SYSTEM FOR OSTEOARTHRITIS OF THE KNEE

BACKGROUND

Osteoarthritis is the most common kind of arthritis. It affects approximately 21 million Americans (MMWR, 2002). There is currently no curative treatment for osteoarthritis, so the major goals of management are to reduce pain and prevent disability.

Treatments currently available for osteoarthritis include analgesic medications, non-steroidal anti-inflammatory drugs (NSAIDs), intra-articular corticosteroid injections, physical therapy, weight loss, use of assistive devices, and various surgical procedures.

The American College of Rheumatology guidelines (ACR subcommittee, 2000) for the treatment of osteoarthritis of the knee recommended use of acetaminophen as first-line therapy, followed by low-dose ibuprofen, and then full dose NSAIDs or cyclooxygenase-2 (COX-2) inhibitors. Although NSAIDs are generally well tolerated, they carry the risk of gastrointestinal bleeding and renal toxicity. Intra-articular corticosteroid injections and topical capsaicin can also be utilized. If the treatment response is inadequate, and the patient is a surgical candidate, then referral for consideration of joint surgery is recommended.

Knee Joint Spacer (UniSpacer™)

The UniSpacer™ is a small, minimally invasive device made of cobalt chrome that fits between the natural bone structures of the knee and stays in place without bone cement or screws. It is geometrically designed to center itself and follow the normal motion of each individual's knee. It allows the surgeon to preserve the patient's bone by replacing only the damaged cartilage and addressing alignment. Because the UniSpacer™ does not require fixation or bone cuts, it does not compromise future conversion to total knee

replacement. The device is reported to relieve arthritic pain and improve joint stability

Knee Joint Spacer (UniSpacer™), continued

by restoring ligament tension and normal knee alignment in patients with osteoarthritis limited to the medial compartment of the knee.

The femoral articulating surface of the UniSpacer™ is cup shaped (concave) to capture the femoral condyle. The tibial surface of the UniSpacer™ is designed to replicate the anatomy of the tibial plateau with the meniscus removed. Since the UniSpacer™ is not fixed in place, it remains centered under the weight-bearing portion of the femur through all angles of flexion. With the UniSpacer™ in place, the ligaments, surrounding the knee are re-tensioned and act as cables that hold the femur against the UniSpacer™.

Figure 1: The UniSpacer™ Device



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The procedure requires only minimal surgical intervention and is performed under general or regional anesthesia and generally takes about one hour. Most patients are able to return to normal activities within a few months.

Knee Joint Spacer (UniSpacer™), continued

Figure 2: X-ray of a knee after placement of the UniSpacer™ device



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The UniSpacer™ was developed for patients who have exhausted traditional treatments for knee pain like drugs and arthroscopy, and are looking for an alternative to knee replacement. More specifically, the UniSpacer™ is indicated for the treatment of isolated, moderate degeneration of the medial compartment (Grade III-IV chondromalacia) with no more than minimal degeneration (Grade



Knee Joint Spacer (UniSpacer™), continued

I-II chondromalacia, no loss of joint space) in the lateral condyle or patellofemoral compartment. These patients typically present with a varus deformity (known as bow-leggedness).

The UniSpacer™ is not suitable for patients with significant patellofemoral disease or significant lateral compartment disease, or those with subchondral bone loss. Furthermore, the anterior and posterior cruciate ligament structures must be intact.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate governmental regulatory bodies.

The UniSpacer™ (Unicondylar Interpositional Spacer [UIS]) received FDA 510(k) clearance on January 4, 2001 as substantially equivalent to predicate devices. “The Unicondylar Interpositional Spacer is intended for uncemented use in treatment of the following:

- Moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.”

TA criterion 1 is met.



TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

There are no peer-reviewed, published studies on the use of the UniSpacer™ device. Specifically, there are no randomized, controlled trials comparing outcomes of surgical placement of the UniSpacer™ device with either sham surgery or conventional, conservative therapy. No published case-series or abstracts were found.

The manufacturer's website contains a report of the effects of the UniSpacer™ on gait parameters in two patients. (Mitchell *et al*, 2002) The gait pattern of both patients was evaluated pre-operatively and approximately 18 months after implantation of the UniSpacer™ device. Measures of forward velocity, step width, and step length improved in both patients after the surgical procedure.

TA criterion 2 is not met.

Level of Evidence: 5, unpublished.

TA Criterion 3: The technology must improve the net health outcomes.

No studies are available with controls to assess the net outcomes after placement of the UniSpacer™ device.

TA Criterion 3 is not met

TA Criterion 4: The technology must be as beneficial as any



Alternative therapies currently available for osteoarthritis include analgesic medications such as acetaminophen, NSAIDs, COX-2 inhibitors, topical capsaicin or methylsalicylate, intra-articular corticosteroid injections and non-pharmacologic measures such as muscle-strengthening exercises, range-of-motion exercises, weight loss, and use of assistive devices such as canes and orthotic braces. Surgical procedures for osteoarthritis include arthroscopic debridement (recently shown to be ineffective [Moseley, 2002]), osteotomy, and total joint replacement.

There are no published data allowing a comparison of insertion of the UniSpacer™ device to established therapies.

TA criterion 4 is not met.

TA Criterion 5: The improvement must be attainable outside the investigational setting.

There are no data available to assess whether improvements are attainable in an investigational setting, let alone in general clinical practice. However, the surgical procedure is not technically demanding and can probably be performed by most orthopedic surgeons after a short training course.

TA criterion 5 is not met

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)



The BCBSA does not have a policy specific to this device or knee implants.

Centers for Medicare and Medicaid Services (CMS)

CMS does not have a coverage position specific to this type of device.

California Orthopaedic Association

A position statement and participation at the meeting have been requested.

American College of Rheumatology

The American College of Rheumatology does not have a formal position on the use of the UniSpacer™. Participation at the meeting has been requested.



CONCLUSION

No published studies are available to assess the safety and efficacy of the UniSpacer™ device. Given the complete lack of evidence, it is particularly concerning that the device has been marketed for the treatment of early osteoarthritis. Any surgical procedure carries risks of anesthesia complications, infection, and venous thrombosis. Surgical placement of knee joint spacer devices requires evaluation in controlled trials in order to assess the efficacy and safety of the procedure before its widespread adoption can be advocated.

At this time, TA criteria 2-5 are not met.

RECOMMENDATION

Surgical placement of a knee joint spacer device (UniSpacer™) for treatment of osteoarthritis does not meet California Technology Assessment Forum TA criteria.

The California Technology Assessment Forum voted to accept the recommendation as written.

February 12, 2003



REFERENCES

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