MEDICAL ACUPUNCTURE
Volume 23, Number 2, 2011

DOI: 10.1089/acu.2010.0775

Double-Blinded, Placebo-Controlled Trial of the Pain-Relieving Effect of Gold Bead Implantation on Cervical Osteoarthritis

Hans Kryger Kjerkegaard, MD,[1,2] Ruth Kirkeby, MD,[1] Thorkild B. Christensen, MD,[1] and Lise Schlünzen, MD[1]

ABSTRACT

Background: Since the 1970s, veterinarians have treated animals with gold implantation at acupuncture points for different chronic joint pain conditions.
Objective: The aim was to evaluate the effect of gold bead implantation on patients with cervical osteoarthritis (CO) in a randomized, double-blinded placebo-control study.
Design, Setting, and Patients: Forty-six patients with X-ray verified CO with chronic pain (visual analogue scale [VAS] ≥ 6) were enrolled in the study.
Intervention: The patients were randomly assigned to 2 groups: Group A ($n = 24$) was treated with gold implantations, and Group B ($n = 22$) received placebo treatment.
Main Outcome Measure: A neurologist (blinded for the treatment modality) determined the VAS-scores and amount of analgesic treatment before and 1 year after the intervention.
Results: In Group A, 16/24 and, in Group B, 2/22 patients stated a marked reduction of their symptoms (consumption of painkillers was reduced by 30% or more) 1 year after the treatment. The VAS score was significantly reduced from 7 (6–9) to 2 (0–9) in Group A ($p < 0.001$) and unchanged (VAS = 7) in group B, 1 year after the intervention.
Conclusions: The present study revealed that the pain-relieving effects of extra-articular gold bead implantation is a promising treatment modality with long-term palliative effects for patients with CO.

Key Words: Gold Implantation, Acupuncture, Analgesia, Osteoarthritis

INTRODUCTION

Cervical osteoarthritis (OA) is a common and painful disease that mainly affects older people, usually over age 40. This condition results from degenerative changes that occur in the cervical spine. Over time, the degenerative changes in the vertebrae can lead to nerve compression or inflammation. Treatments for neck pain are varied, as are the perceptions of benefits. Conventional treatment is usually with medication and the use of a cervical collar. However, if this fails, then surgery may be necessary.

Acupuncture has been used as an alternative to more conventional treatments for cervical OA, but the improvement is often short-lasting.[1] The idea of producing a lasting acupuncture stimulus was started in the 1970s by American veterinarians who implanted gold beads in dogs suffering from acetabular dysplasia.[2] Two recent articles have revealed that gold bead implantation has a significant pain-relieving effect in a 6-month and a 2-year controlled

[1]The Danish Medical Association of Acupuncture, Copenhagen, Denmark.
[2]Gold Implant Clinic, Åarhus, Denmark.
The present work has been presented at the International Council of Medical Acupunture and Related Techniques (ICMART) Congress, September 10–12, 2008.

double-blinded trial in dogs with hip joint arthritis.[3,4] So far, only one human study on gold implantation is available. This double-blinded, randomized controlled trial reported lasting reduction (1-year outcome) of symptoms after gold bead implantation in patients with knee OA.[5]

The aim of the present study was to evaluate the effect of gold bead implantation on patients with cervical OA. This was a randomized, double-blinded placebo-controlled study in a group of patients with cervical OA from 2002 to 2004.

METHODS

This study was approved by a regional committee on ethics in medical research. All patients gave written consent to participate in the study after the procedure had been extensively explained verbally and in writing.

When the randomization code was broken, the placebo-treated patients were offered gold bead implantation, which all patients accepted.

Participants

The criteria for inclusion were: (1) clinical and radiologically verified cervical OA; (2) age $\geq$30 (3) pain from cervical OA for longer than the last 12 months; (4) no lasting effects of previous treatments (e.g., physical therapy, chiropractic manipulation, or other manual therapy); and (5) pain symptoms amounting to at least 6 on a visual analogue scale (VAS) from 0–10. The criteria for exclusion were: (1) ongoing analgesic treatment for other ailments; (2) severe somatic or mental illnesses; (3) rheumatoid arthritis; (4) arthritic lumbar symptoms; (5) previous surgical cervical spinal treatments; (6) whiplash-associated disease; (7) alcohol or prescription abuse; and (8) pregnancy.

Five hundred patients came forward to participate in the study. According to the inclusion and exclusion criteria, 55 were enrolled in the study and were considered to be suitable for randomization (Fig. 1). Their main symptoms were chronic neck pain often related to headache, pain in shoulders and arms, or upper thoracic region. The population of the study was divided in a gold and a non-gold group in a double-blinded randomization procedure, performed by drawing an envelope with information stating which group each patient was assigned to, as described later in the procedure.

The Research Process

The patients' suitability for this research project was determined on the basis of the abovementioned criteria during the first visit to a neurologist (Dr. I). In addition, the intensity of neck pain was evaluated using the VAS scale, and use of painkillers was recorded (Fig. 2).

Dr. II provided the second consultation (Fig. 2). Based on segmental diagnosis, where the tender segments were found, the level of gold implantation was determined for patients in the intervention group (Fig. 3). In this form of diagnosis, the affected segments at the Hua Tua points will be tender to

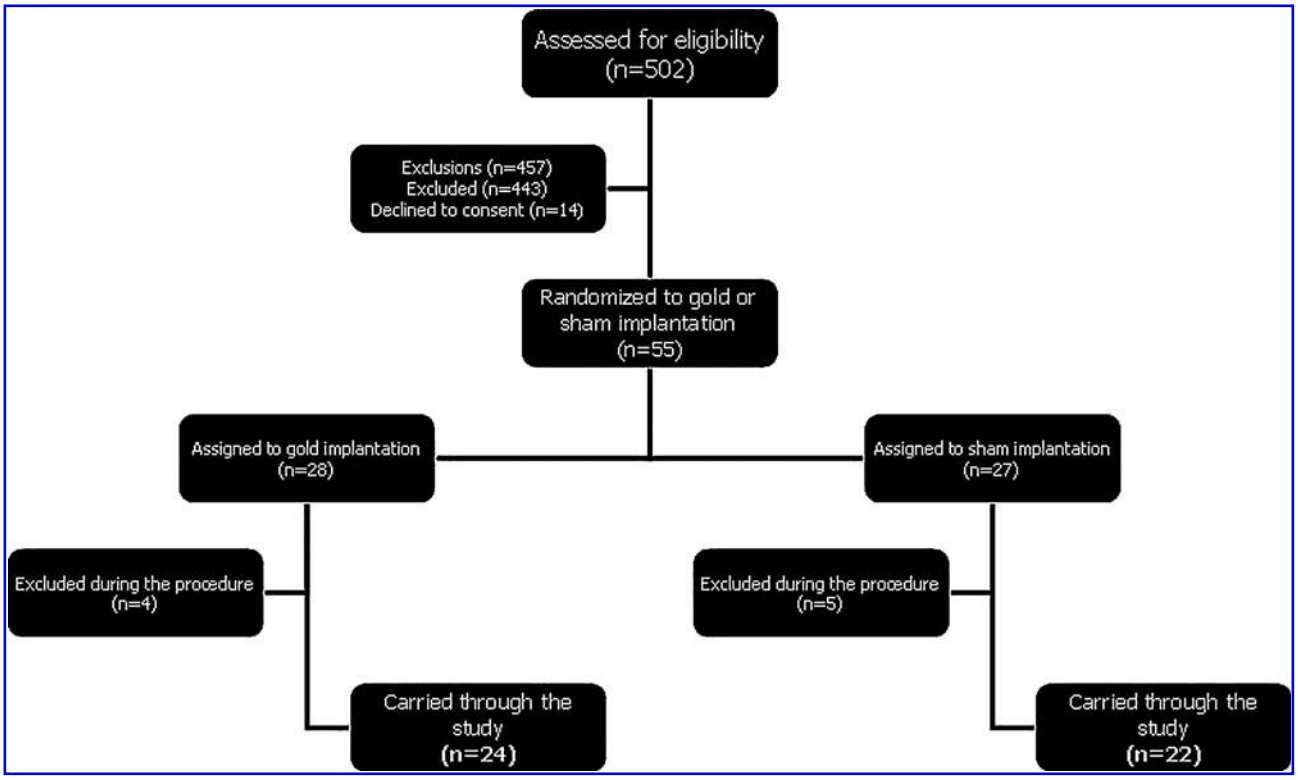

FIG. 1. Flow of participants through trial.

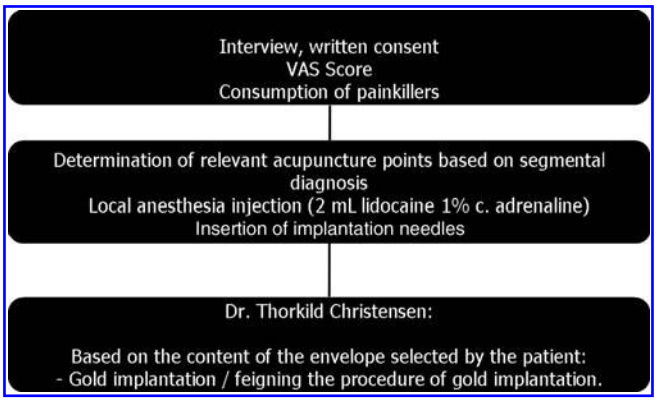

FIG. 2. The research process.

deep palpation.[6] The Hua Tua points correspond to the paraspinal anatomical areas supplied by the medial dorsal ramus of the spinal nerves. These areas will be tender if any pathological signal is arriving to the corresponding segment, whether it is coming from the myotome, sclerotome, dermatome, or viscerotome.[6] Local anaesthesia with lidocaine *cum* adrenalin (10 mg/mL +5 mμ/mL) was injected in each selected point. This procedure resulted in immediate pain relief if the correct segmental levels were treated. Empirically, it is known that only patients, who achieve this pain relief after injection of local anaesthesia, will obtain a positive result from gold implantation. The immediate effect of these initial injections was determined based on the patients' subjective evaluation. Accordingly, 4 patients in both groups were excluded from the study because of lack of pain relief after injection of local anesthesia (Fig. 1). Furthermore, 1 patient had to be excluded in the placebo group during the trial because of progressive senility. The research sample subsequently consisted of 46 patients, including 20 males and 26 females (Fig. 1). In those 46 patients, implantation needles were gently inserted in the selected Hua Tua points until they reached the lamina region of the vertebrae (Fig. 3). This procedure was performed by Dr. II, and then Dr. II left the room. An envelope previously selected by the patient containing a piece of paper, stating whether the patient was to receive gold or not, was opened. If the patient had drawn an envelope with "gold," Dr. III would follow-up with gold implantation with cylindrical beads of 24-carat gold measuring 1×2.5 mm with an average weight of 35 mg through the already inserted implantation needles. Three gold beads were implanted through each needle (Fig. 4). To be sure that the gold beads remained at the intended position, an introducer was pushed in while the implantation needle was removed (Fig. 5). In this way the gold beads were placed close to the lamina region of the vertebra. If the patient had drawn an envelope stating "no gold," Dr. III would feign the procedure of gold implantation (Fig. 2). Twenty-four patients were randomized to the "gold implantation" group

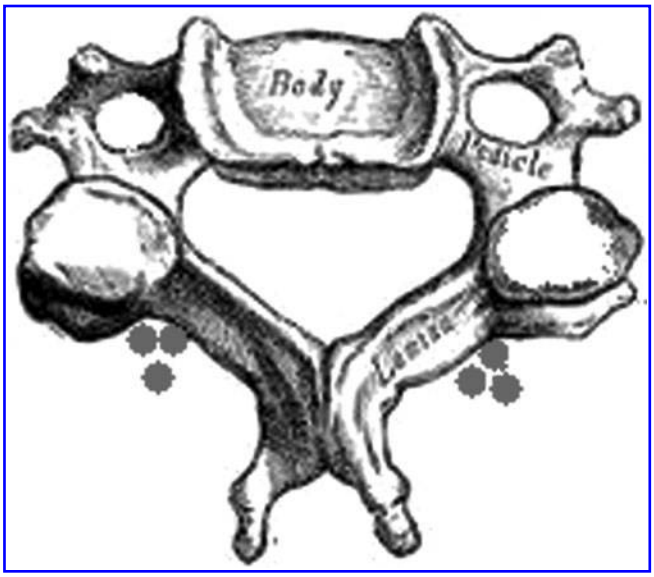

FIG. 3. Location of the implanted gold beads.

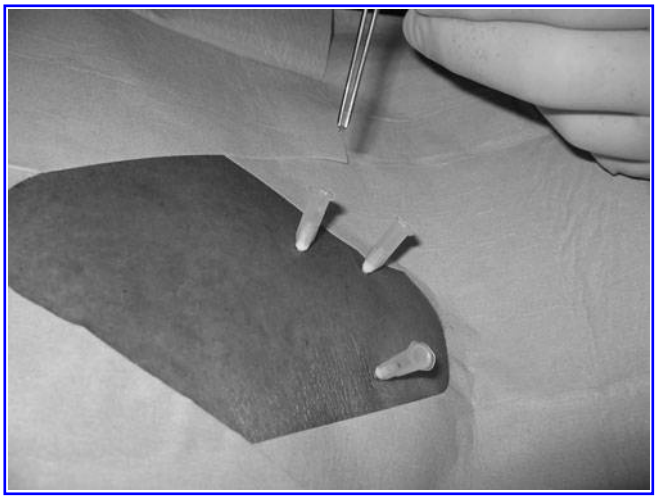

FIG. 4. Three gold beads are inserted in each implantation needle.

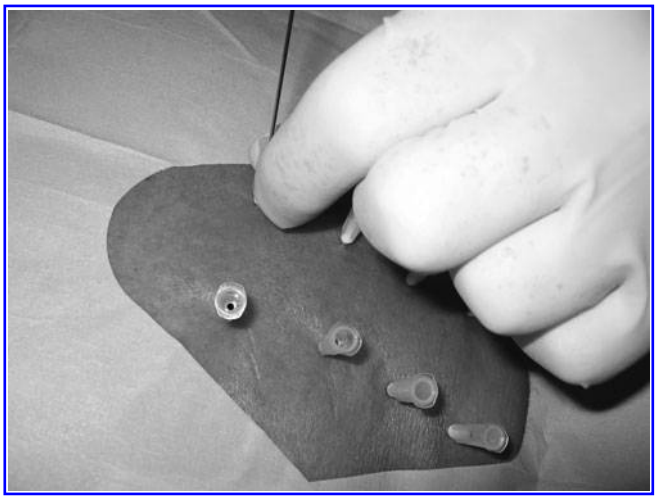

FIG. 5. An introducer is pushed in while the implantation needle is removed.

Table 1. Baseline Characteristics of Patients with Cervical Osteoarthritis, Randomized to Gold Implantation or Sham Implantation

Characteristics	*Gold implantation (n = 24)*	*Sham implantation (n = 22)*
Men/women	10/14	10/12
Age (years)	54 (34–70)	52 (30–68)
Duration of symptoms (years)	8 (5–11)	6 (4–8)
VAS score	7 (6–9)	7 (6–9)

Values are numbers or medians (ranges).
VAS, visual analogue scale.

and 22 patients were randomized to the "sham implantation" group (see Fig. 1 for flow of participants through the trial). Baseline characteristics of the patients in the 2 groups are listed in Table 1. Both groups were treated equally with respect to anesthesia and penetration of the skin with the same type of needle. The patients were blinded to the procedure as they were lying prone during that time.

Outcome Measures

One year after the gold implantation, the same neurology specialist (Dr. I), who was still blinded to the randomization, evaluated the patients' arthritic neck pain using the VAS scale and each patient's use of painkillers was registered. For each patient, change of analgesic requirements, expressed as a percentage, was estimated. If the use of painkillers was reduced by at least 30%, compared with use prior to the treatment, the result was, by definition, regarded as successful.

The randomization list was opened after the final evaluation at the commencement of data analysis.

Statistics

The results were noted as medians (ranges). The Mann-Whitney *U*-test (non-parametric) was used to gauge the difference in 12-month outcomes between the treatment groups. The level of statistical significance was $p < 0.05$.

RESULTS

At the start of the study, the patients in the intervention and control groups had similar characteristics (Table 1).

In the gold implantation group, the mean VAS-score recorded by the clinical investigator was significantly reduced from 7 (6–9) to 2 (0–9) from day 0 to month 12 ($p < 0.001$). The VAS score in the placebo group remained unchanged (Fig. 6).

In the gold implantation group, 16 patients reduced their use of analgesics reduced by ≥30%, 3 patients reduced their use by 10%–29%, and 5 patients reduced their use of analgesics by <10%. For the placebo group, the numbers of patients who reduced their analgesic use were 2, 2, and 18, respectively (Table 2).

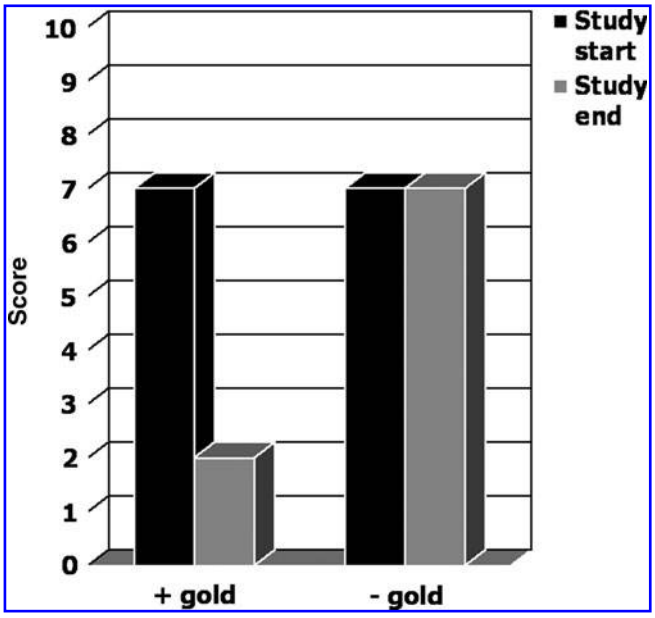

FIG. 6. Pain score (visual analogue score [median]) at study start and study end of patients with cervical osteoarthritis, who were randomized to gold implantation or sham implantation.

No side-effects were observed, and no patients in the gold implantation group experienced any worsening of their symptoms.

DISCUSSION

This 1-year double blinded, randomized control trial of gold bead implantation demonstrated a statistically significant reduction in pain score and analgesic use in patients with cervical OA. The treatment was well-tolerated and caused no side-effects.

Gold bead implantation is an experimental area of study in the acupuncture treatment for chronic degenerative diseases. It is, however, remarkable that a one-time implantation of gold beads should have such a sustained pain-relieving effect over so many months. A recent critical review of randomized control trials comparing acupuncture with placebo for chronic mechanical neck disorders indicated moderate evidence that acupuncture relieves pain better than sham treatments.[7] A literature search only identified one human

Table 2. Patients' Who Were Randomized to Gold Implantation or Sham Implantation Self-Reported Use of Analgesics at Study End, Compared with Study Start

Painkiller consumption	*Gold implantation (n = 24)*	*Sham implantation (n = 22)*
Reduction ≥30%	16	2
Reduction 10%–29%	3	2
Reduction <10%	5	18

Values are number of patients.

study of gold bead implantation in the treatment of OA,[5] but, in veterinary medicine, this treatment has been used for >30 years, and clinical trials have demonstrated a positive, long-term, and sustained palliative effect as assessed via physical activity, eating patterns, and signs of pain.[2–4]

Both the gold group and placebo group were well-matched demographically for age, pain severity, and duration and degree of associated symptoms. The dropout rate was low, and it was not possible for the patients to determine whether they had received gold beads implanted or not, as they were lying prone, unable to observe or feel whether gold was implanted or not. The patients, however, were not asked at the end of the treatment if they felt they had gold implanted or not, which may be a limitation of this study.

The local anesthesia injected in the selected Hua Tua points, was used as a guide for proper selection of points to treat. If the injected local anesthesia resulted in immediate pain relief, the correct segmental levels were treated. In the absence of pain relief, gold implantations would not lead to any beneficial effects, as the beads were not implanted at the level of pain origination. In both groups, 4 patients had to be excluded because of lack positive response to the local anesthesia. So, approximately 17% of the patients were found to be not suited for gold implantation.

It may be hypothesised that gold bead implantation at acupuncture points acts as a continuous acupuncture stimulation. Twenty-four carat gold is non-toxic and does not prevent later spinal surgery. However, gold ions are released from the implanted gold and diffuse out into the surrounding tissue.[8] The gold-containing cells in connective tissues are macrophages, mast cells, and fibroblasts.[8] The findings suggest that gold implantation technique, on a local scale, mimics systemic treatment with a gold-containing drug. It is, however, impossible to say whether it is this phenomenon or the hypothesised continuous acupuncture stimulation that contributes mostly to the pain-relieving effect of gold bead implantation.

A limitation of this study was that the effects of the intervention were only determined after 1 year, and not every month or every second month. This lack of time framework information made it impossible to tell when the analgesic effect of the gold implantation began or reached its peak. A trial comparing gold implantation with sham in humans with from OA in the knees, demonstrated that the effect of the gold implantation reached its maximum after 3 months with no clear trend toward increasing or decreasing after this time.[5]

No patients developed infections, rejection, or discomfort related to the implanted gold. X-rays obtained years after the implantation of gold have demonstrated that the implants are still situated in the exact location where they were implanted.[4,5] However, migration of embedded permanent acupuncture needles has been described in the literature, which has articles about implanted needles that have migrated to the spinal cord, lung, and heart.[9–11]

CONCLUSIONS

The present study revealed that the pain-relieving effects of extra-articular gold bead implantation is a promising treatment modality with long-term effects for patients with cervical OA. The gold implantation procedure requires extensive experience with special acupuncture techniques and needs to be done with the same accuracy as any other surgical treatment.

DISCLOSURE STATEMENT

Hans Kryger Kjerkegaard is performing gold bead implantation in his private clinic.

REFERENCES

1. Trinh K, Graham N, Gross A, Goldsmith C, Wang E, Cameron I, Kay T. Acupuncture for neck disorders. *Spine*. 2007;15:236–243.
2. Durkes TE. Gold bead implants. *Probl Vet Med*. 1992;4:207–211.
3. Jaeger GT, Larsen S, Soli N, Moe L. Double-blind, placebo-controlled trial of the pain-relieving effects of implantation of gold beads into dogs with hip dysplasia. *Vet Rec*. 2206;158:722–726.
4. Jaeger GT, Larsen S, Soli N, Moe L. Two years follow-up study of the pain-relieving effect of gold bead implantation in dogs with hip-joint arthritis. *Acta Vet Scand*. 2007;49:(9):31–38.
5. Nejrup K, Olivarius N, Jacobsen JL, Siersma V. Randomised controlled trial of extraarticular gold bead implantation for treatment of knee osteoarthritis: a pilot study. *Clin Rheumatol*. 2008;27:363–369.
6. Bekkering R, Bussel R. Segmental acupuncture. In: Filshie J, White A, eds. Medical Acupuncture: A Western Scientific Approach. Philadelphia: Churchill Livingstone; 1988:105–135.
7. Trinh KV, Graham N, Gross AR, Goldsmith CH, Wang E, Cameron ID, Kay T. Acupuncture for neck disorders. *Cochrane Database Syst Rev*. 2006;19:CD004870.
8. Danscher G. *In vivo* liberation of gold ions from gold implants: autometallographic tracing of gold in cells adjacent to metallic gold. *Histochem Cell Biol*. 2002;117:447–452.
9. Abumi K, Anbo H, Kaneda K. Migration of an acupuncture needle into the medulla oblongata. *Eur Spine J*. 1996;5:137–139.
10. Von Riedenauer WB, Baker MK, Brewer RJ. Video-assisted thorascopic removal of migratory acupuncture needle causing pneumothorax. *Chest*. 2007;131:899–901.
11. Kim YJ, Kim JY, Choi BW, Nam JE, Kim TH, Choe KO. Images in cardiovascular medicine: right ventricular acupuncture needle embolism detected on coronary computer tomography angiography. *Circulation*. 2006;114:e623–e626.

Address correspondence to:
Hans Kryger Kjerkegaard, MD
Gold Implant Clinic
Kystcentret i Egå
Skæring Strandvej 3
8250 Egaa, Åarhus
Denmark

E-mail: gold.doc@mail.dk