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Two-peg versus flat tibial tray design in cemented unicompartmental knee arthroplasty

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Summary

Objective. Suboptimal fixation of the tibial component is one of the main factors leading to aseptic loosening in unicompartmental knee arthroplasty (UKA). Improvements in primary fixation in cemented UKA have been suggested to be a key issue for long-term survival. In this context, it has been questioned whether specific implant design features influence interface strength, lowering aseptic loosening and post-operative pain rates. The aim of this study is to compare two different tibial tray designs in cemented UKA in terms of clinical outcome, failures, implant survival, and complications.

Materials and methods. This is a prospective consecutive study of two different tibial component fixation in 100 cemented UKA. 50 patients received a flat cemented tibial tray design, and 50 a two-peg cemented tibial component UKA. Both groups were similar in terms of age, sex, comorbidities, and BMI.

Results. No significant difference was found in clinical outcomes and overall failure rates. In the flat tray group, the mean preoperative KSS was 57.2, which increased at 1-year follow-up after surgery to 92.28, and remained stable at the 3 and 6 year control visits. In parallel, the mean pre-operative KOOS of 59 increased to 87.20. The mean preoperative KSS score in the 2 pegs group was 56.8 and the mean KOOS 58.1. At 1-year follow-up the KSS score increased to 94.1 and the KOOS score to 89.22, remaining stable at the 3- and 6-year follow-ups. Two-peg tibial component showed a significantly lower rate of persistent pain on the tibial side, 8% of patients at 1 year follow-up and 2% at 2 years, compared to 20% at 1 year and 6% at 2-year follow-up in the flat tray group ($p < 0.05$). In both groups, patients with pain at the 2-year control, 4 patients in total, still complained of mild and intermittent pain, VAS 1 to 2, at the 6 year visit. There was also a lower incidence of radiolucent lines compared to flat design prosthesis, none versus 6 at 3-yeas radiographic control. Radiolucent lines were not related to pain. No difference was detected regarding range of motion between the two groups.

Conclusions. This study reveals that the clinical results and failure rates arising from the use of two different tibial components, one flat and one with 2 pegs, are similar. However, a lower rate of pain and radiolucent lines are detected on the tibial side with the use of a two-peg tibial component design. This outcome could denote a better fixation of the 2 peg metal-backed tibial component implant.

Key words: unicompartmental knee arthroplasty, fixation, implant design, pain, radiolucent lines

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Introduction

Unicompartmental knee arthroplasty (UKA) is recognized as a reliable treatment for isolated medial or lateral arthritis. Very good results have been reported, even after

20 years of follow-up [1]. Classical indications, however, need to be strictly observed in order to ensure satisfactory results: varus deformity not greater than 15°, intact ACL, asymptomatic patello femoral joint, minimum ROM 100°, and no flexion deformity over 10°. The good results led to a widening of the indications so that UKA is currently implanted even in patients younger than 60 years [2], or with a BMI above 30 [3]. The success of UKA is related to advances in the design of prosthetic components and improvements in materials, to the point that failures today are mostly due to progression of degenerative involvement in the initially free compartment [4]. While these failures are probably due to a wrong indication or to an incorrect polyethylene thickness, other complications as aseptic loosening, persistent unexplained pain, tibial component subsidence, and radiolucency lines, are rather related to tibial component fixation.

Improvements in primary fixation in cemented UKA have been suggested to be a key issue for long-term survival. It has been questioned whether specific implant design features influence interface strength, lowering the chance of aseptic loosening and postoperative pain rates. In recent years, the best implant suitability between all polyethylene (AP) and metal backed (MB) tibial component has long been debated. Finite element analysis demonstrated that AP implants exhibited significantly higher strain measurements compared to MB implants [5]. Pain has been related to increased adoptive bone remodeling on the tibial medial metaphysis following the implant [6]. MB tray was supposed to be the best solution because of its demonstrated capacity of decreasing tibial strains through a more homogeneous distribution. Our observation of patients still complaining for pain after surgery, even if treated with MB trays, suggested the need to replace the MB component with a flat surface with a different implant, with 2 pegs. In our opinion, a more rigid system should have ensured a better stress distribution and reduced pain. The aim of this study is to compare two different tibial tray designs, one flat and one with 2 pegs, in cemented UKA in terms of clinical outcome, failures, implant survival, and complications.

Materials and methods

The study is a prospective non-randomized review of 100 consecutive patients with isolated medial arthritis treated with UKA in the period from March 2012 to June 2015. The first series of 50 patients had an Accuris Uni Knee System, Smith & Nephew, cemented UKA implanted, with a flat metal backed tibial component, while the second series of 50 patients had a Triathlon Partial Knee Replacement, Stryker, cemented UKA implanted, with a 2 peg tray (Fig. 1). All surgeries were performed by a single surgeon.

Mean follow-up for the flat tibial component was 9 years, (minimum 8-maximum 10 years) and 6 years for the 2 peg tibial component (minimum 6-maximum 7 years). Demographic data showed similar age, sex, distribution, and BMI. No major comorbidities were reported in both groups. The mean age for

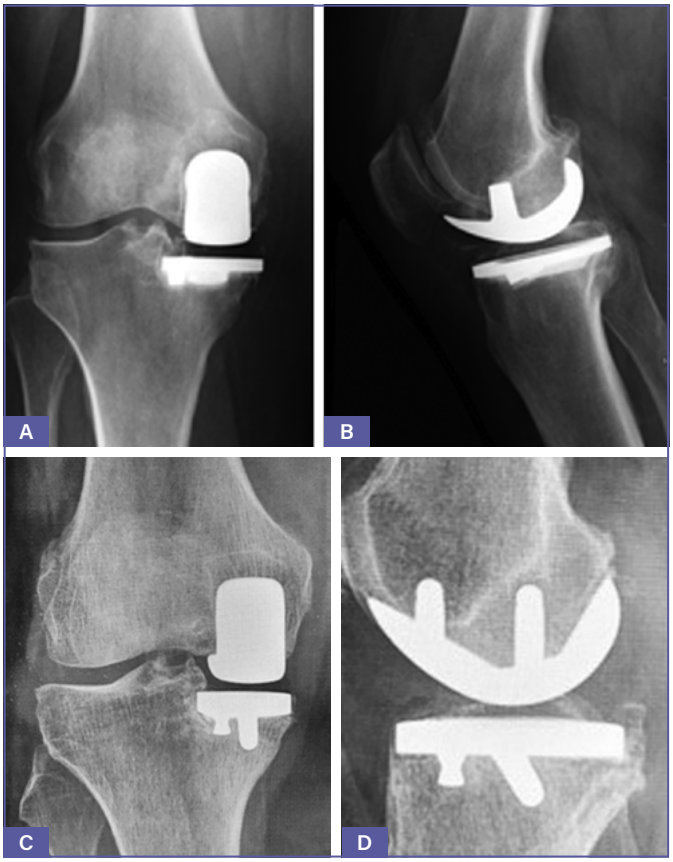
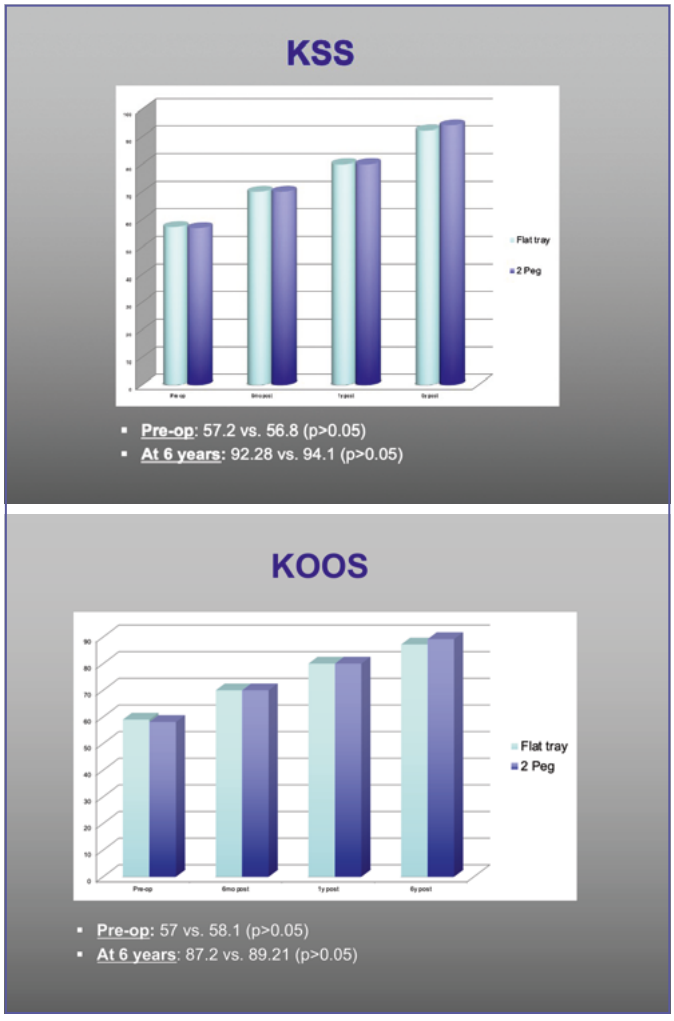


Figure 1. The two different tibial tray components. A,B) flat tibial component. Follow-up at 7 years; C,D) two peg tibial component. Follow-up at 6 years.

the flat tray component group was 69 years (group 1), and 72 for the 2 peg tibial component group (group 2). Group 1 was composed of 32 females and 18 males patients, while group 2 presented 30 females and 20 males. Mean BMI for group 1 was 28.45 (23.6-32.10), and 29.13 (22.9-31.9) for group 2.

The same strict selection criteria were adopted for both series: varus deformity not greater than 15°, intact ACL, asymptomatic patella-femoral joint, minimum ROM 100°, and no flexion deformity over 10°. Pre-operative scores of the two series were not significantly different. All patients were evaluated according to KSS and KOOS scores. Preoperative KSS score was 57.2 (34-60) for group 1 and 56.8 (35-59) for group 2. Preoperative KOOS values were 57 for group 1 (40-72), and 58.1 for group 2 (40-72). The grade of arthritis (OA) was detected and classified according to the Kellgren and Lawrence Grading Scale [7]. In all, 42 patients had KL grade 3 OA and 8 grade 4 OA in group 1, and 44 had KL grade 3 OA and 6 grade 4 OA in group 2. All UKA were implanted through a minimally- invasive approach. All 100 patients were routinely mobilized, fully weight-bearing on the first or second postoperative day, and discharged on third day. No major post-operative complications were registered.



Figures 2-3. Evaluation according to KSS and KOOS scores. Pre-operative values are not significantly different. The scores of the 2 groups at 6 months, 12 months, and 6 years follow-up are also very similar.

Results

Clinical evaluation was based on the KSS and KOOS scores. Moreover, VAS score and ROM were investigated at every control. Radiolucent lines (RLLs) at the implant-bone interface were assessed on plain radiography at 6, 12, 36, and 72 months. Aseptic loosening, persistent unexplained pain, intra- and post-operative tibial fractures, and tibial component subsidence, were recorded up to a minimum follow-up of 6 years. No significant difference was found in clinical outcomes and overall failure rates.

In the flat tray group, the mean postoperative KSS increased to 92.28, from 57.2, at 6 year or longer follow-up, and the mean post-operative KOOS increased to 87.20 from 57. The mean pre-operative KSS score in the 2 pegs group was 56.8 and the mean KOOS was 58.1. At 6 years follow-up the KSS score increased to 94.1 and the KOOS score to 89.22 (Figs. 2-3).

No significant differences in failure rates were seen between the two groups. In the flat tibial tray (group 2), 2 patients required revision: 1 for aseptic loosening and 1 for medial tibial plateau fracture. In the two-pegs group there was only one complication, a medial tibial plateau fracture that required revision, but no cases of aseptic loosening.

Pain was evaluated with the VAS scale. VAS 0, 1 or 2 was interpreted as absence of pain. Two-peg tibial prosthesis showed a significantly lower VAS score. Persistent pain, VAS ≥ 3, was reported in 20% of patients at one year and in 6% at 2 years in the flat tray group, and in 8% of patients at one year and 2% at 2 years in the two-peg implants (Mann-Whitney test, p = 0.052) (Fig. 4). The differences in VAS scores in the 2 groups, significant at 1 year, became insignificant at 2 years (Mann-Whitney test, p = 0.112).

The percentage of patients VAS ≤ 2 with 2 years f.u. was 98% in the group treated with a two-peg tray, and 94% in the flat tray group (p = 0.307) (Fig. 5). The results did not differ at subsequent controls.

Radiographs were obtained at each visit to evaluate component alignment, radiolucencies, or loosening. Radiolucent lines were detected in 12% of patients treated with flat tray design tibial component, and none in the 2 pegs tray. Moreover, radiolucent lines in all patients were not related to pain (Fig. 6).

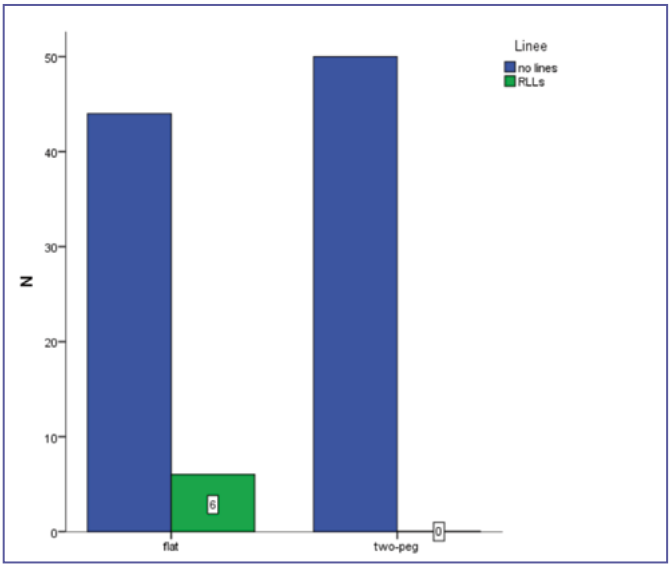


Figure 4. VAS scores. Follow-up at 1 year. The two columns on the left report data regarding pain-free patients or with VAS < 2. The column on the right reports patients with VAS 4, 5, and 6. The percentage of patients who were pain-free or with VAS < 2 is significant in patients of two peg tray group compared to flat tray group (Mann-Whitney test p = 0.052).

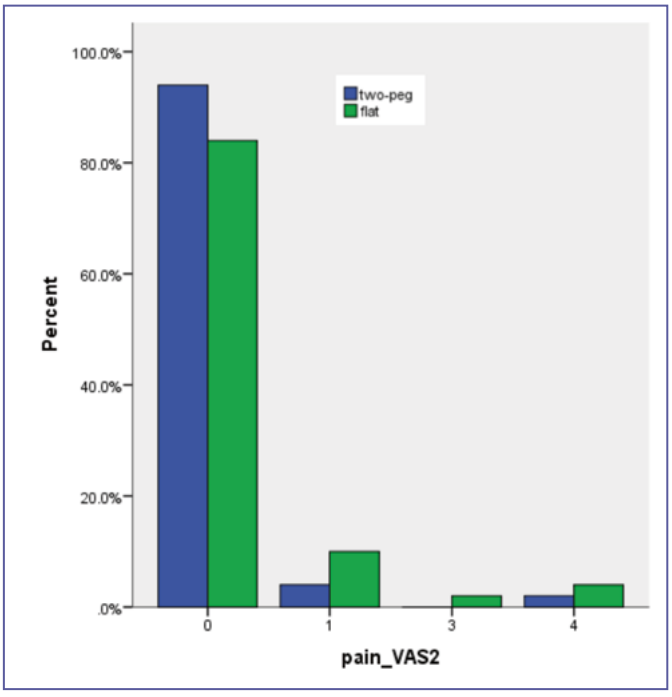


Figure 5. VAS scores. Follow-up at 2 years. Distribution of scores are similar at 2 years follow-up and difference between the 2 groups is no longer significant (Mann-Whitney test p = 0.112). The columns on the left show the percentage of pain-free patients or with VAS < 2 which in the two peg group is 98% and in the flat group is 94%. The values do not change in subsequent controls.

No significant difference was seen in ROM between the two groups, with mean ROM 127° (+- 12) in the flat tray group and 128° (+-11) in the 2 peg group (Fig. 7). The maximum ROM was detected at 2 years. After this time, no additional progression was observed.

Discussion

Suboptimal fixation of the tibial component is one of the main factors leading to failure in UKA. Improvements in primary fixation in cemented UKA have been suggested to be a key issue for long-term survival. Through this prospective and non-randomized study, 2 different tibial components, both cemented metal backed, were compared in terms of clinical outcomes, implant survival, complications and failures; a flat tray *versus* a 2 pegs tray. No previous studies comparing two different cemented metal backed surfaces have been reported. Six years as a minimum follow-up is a too short period of time to evaluate implant survivorship. However, it can be considered long enough to compare clinical results, mostly pain and prevalence of early failures, between 2 different implants.

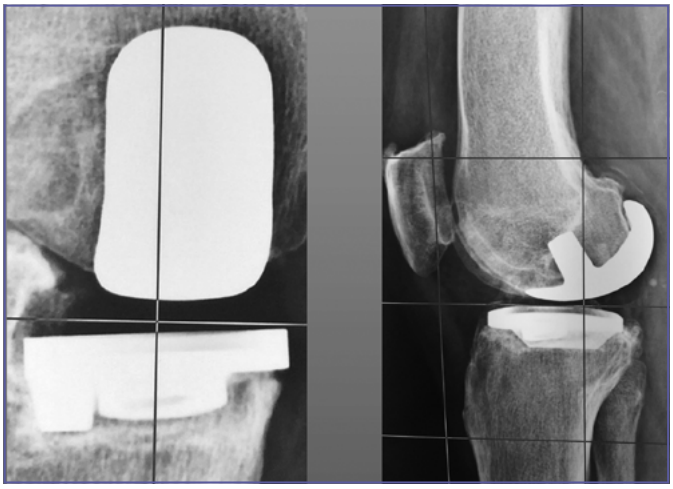


Figure 6. Complete radiolucent lines involving only the tibial component. Radiolucent lines were never related to pain in our series. Radiolucent lines were detected at 6 year follow-up only in the flat tray group, 12% *versus* 0, in the two pegs group (Fisher Exact test, p = 0.013).

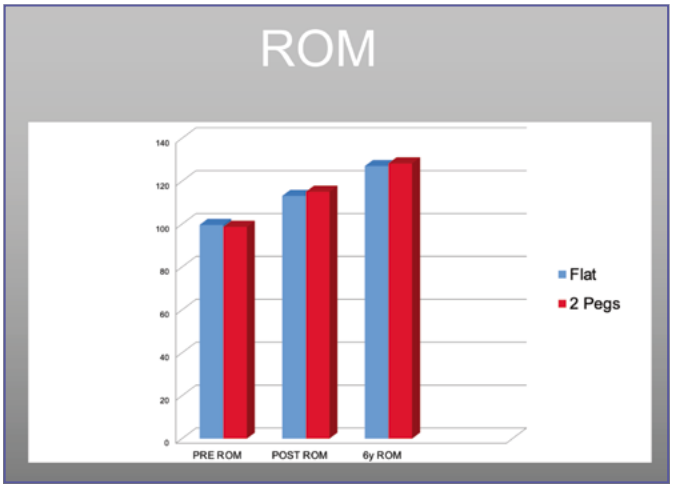


Figure 7. Comparison of range of motion in the 2 groups. Results were very similar at 2-year follow-up. Values were unchanged at 6 years of follow-up.

Revision was required in 3 patients: 2 in the flat tray group and 1 in the 2 pegs group. One patient in each group required revision for medial tibial plateau fracture. The fracture, tibial collapse, in the flat group was diagnosed 25 days following surgery and immediately converted to a primary TKA. Even the case of medial tibial fracture in the 2 pegs group occurred early postoperatively, 30 days, following a slight trauma but needed a revision to TKA with stems and wedges. This female patient was 58 years old with a BMI of 34. The second patient in the flat tray group required revision for aseptic loosening,

detected at 2 years and converted to a primary TKA. In the two-pegs group there were no aseptic loosening cases, but the difference was not statistically significant.

One additional unresolved problem about UKA is unexplained pain. It is reported as cause of revision in 24 to 48% of UKA failures [6]. The National Norwegian Registry in 2015 reported revision for pain in 27% of cases, placing pain as the second cause of failure after progression of osteoarthritis in the initially unaffected compartments. Only a few years before, in 2013 and 2014, according to the same Registry, unexplained pain was the first cause of revision [8]. In another series, Pandit reported revisions for pain in 0.6% of patients of a total of 2.9% revisions in a series of 1000 Oxford phase 3 UKA [9]. Pain is usually localized to the antero-medial region of the proximal tibia. Simpson demonstrated that bone strain increases by 40% following UKA. As the bone remodels over time, this strain will decrease, and the same occurs for pain that usually settles down within 12 months after surgery. Bone strain differs depending on the material of tibial component, all poly or metal backed [10]. In a finite element study, Scott observed greater volumes of pathologically overstrained cancellous bone following an AP tibial component rather than a MB one [6]. Elevated proximal tibial strain and micro damage are supposed to be the origin of the pain.

Pain analysis was conducted through a standardized visual analogue scale (VAS), where patients rated their current pain ranging from 0 to 10 [11]. In group 1, pain was reported by 20% of patients after 1 year and by 8% after 2 years. In group 2, pain was reported by 6% of patients after 1 year and by 2% after 2 years.

This study therefore highlights a significant difference in pain during the first year after surgery when comparing two different fixation surfaces, one flat and one with 2 pegs. This difference become insignificant after 2 years and did not change at later times.

This study suggests that both conditions, different materials, AP *versus* MB, and different surface fixation, can influence pain. A more stable fixation could reduce bone remodeling, and, consequently, pain.

Radiolucent lines are commonly observed at the bone-implant interface of UKA tibial components. In the post-operative course, they can be misinterpreted and perceived as signs of loosening, thus leading to unnecessary revisions. Physiological radiolucent lines are usually < 2 mm thick and have a dense sclerotic margin. Gulati reports complete radiolucent lines in 30% of patients, and partial in 32% of patients at 5 years after surgery with Oxford UKA [12]. In a study comparing cemented and uncemented UKA, Panzram reported radiolucent lines in about 30% of uncemented cases after 3 months. They however decreased to 15% after 3 years and to 10% after 5 years. Results between cemented and uncemented implants were similar at 5 years [13].

Recent studies showed a significantly lower incidence of radiolucent lines in cementless than in cemented UKA. For instance, in the largest study concerning 1000 cementless Oxford implants, Liddle showed a radiolucent line rate of 8.9% [14]. Hooper detected only 3 cases with radiolucent lines in 196 knees within the first two years after implantation [15]. In a prospective randomized trial, Pandit demonstrated the presence of partial tibial radiolucent lines in only 7% of cases in the cementless group, compared to 75% (43% partial) in the cemented group [16].

Their etiology remains unclear, even if it must be stressed that radiolucent lines are not a source of adverse symptoms or pain. In our series, they were present in the flat tray group only, 12 *versus* 0% in the two peg group (Fisher's exact test, p = 0.013).

Conclusions

Excellent clinical results in both groups herein confirm the success of flat and 2 pegs tibial tray components. A different tray fixation in our experience does not involve a significant difference regarding KSS, KOOS score, and ROM. These data are in accordance with the literature. A significant difference was reported in VAS scores and the presence of RLLs.

Persistent pain, VAS ≥ 3, usually located on the tibial side, was reported by 20% of patients in the flat tray group *versus* 6% in the 2 pegs tray at 1 year (Mann-Whitney test, p = 0.112). The difference was no longer significant in subsequent clinical visits. Radiolucent lines were detected only in the flat tray tibial component with a percentage of 12 *versus* 0% (p = 0.013). In no case were they related to post-operative pain.

Complications in the two groups were not significantly different. For first time, this study compares two different fixation surfaces, one flat and one with 2 pegs, in terms of loosening, pain, and radiolucent lines. Limitations however include the small sample size and the relatively short term follow-up. Additional studies in the future, with a longer follow-up period, will enable to definitively establish the best fixation surface for tibial component.

Conflict of interest statement

The authors declare no conflict of interest.

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Author contributions

The Authors contributed equally to the work.

Ethical consideration

This retrospective cohort study was conducted at Fatebenefratelli Hospital, Isola Tiberina, Gemelli Isola, Roma in compliance with the declaration of Helsinki.

All participating patients signed an informed consent regarding the procedure, possible complications and alternative treatments modalities.

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