Peri-Apatite™ Enhances Prosthetic Fixation in Tka-A Prospective Randomised RSA Study

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Abstract

Objectives: The success of non-cemented knee fixation relies on the initial stability of the components. The application of ceramic coatings such as hydroxyapatite (HA) to the implant shortens the time needed to achieve adequate prosthetic fixation. The purpose of this study was to determine whether a low temperature precipitation technique, Peri-Apatite™ HA coating, reduces three-dimensional migration compared with porous coated press-fit tibial components.

Methods: Sixty patients were prospectively randomised to receive either a Peri-Apatite™ or a porous coated version of the same knee prosthesis type. Three-dimensional tibial component migration was measured by radiostereometric analysis (RSA) at three months, one year and two years; clinical outcome was measured by the American Knee Society Score (AKSS) and Knee Osteoarthritis and Injury Outcome Score (KOOS).

Results: The Peri-Apatite™ coated prostheses had a lower Maximum Total Point Motion than the uncoated prostheses. There were fewer Peri-Apatite™ coated prostheses showing continuous migration.

Conclusions: The short term RSA findings demonstrate that Peri-Apatite™ coating improves early implant stability.

Level of evidence: Level I.

Keywords: Peri-Apatite coating; RSA; Fixation; TKA; Stability

Introduction

Cemented fixation is the most used method of fixation for TKA components. The success of fixation is reliant on the initial fixation of the components [1]. The presence of progressive early implant micro-motion is predictors of implant failure for both cemented and non-cemented prosthesis [2,3]. During the last decades, roentgen stereo photogrammetric analysis (RSA) has emerged as a way to assess prosthetic fixation [4,5]. The method has been used both in hip and knee arthroplasty and has been shown to serve as an early predictor of late mechanical loosening both for knee and hip prostheses [2,6].

RSA studies comparing the initial stability of non-cemented tibial components have shown a lower initial mechanical stability, compared to cemented components, which may compromise their success [7] despite the stabilisation occurred during the first three months [8], however, the prevalence of non-cemented fixation is increasing due to its advantages of increased bone preservation and durable long-term fixation [9-11]. This fixation is achieved by osseous integration between the bone and implant surface, successful osseo-integration is characterised by the absence of progressive implant micro-motion [2,12], absence of radiolucent lines, and the presence of bone remodelling adjacent to the prosthesis [13,14].

The initial fixation of non-cemented components can be improved by careful surgical site preparation; by ensuring a press-fit between the implant and the bone; and by the application of ceramic coatings such as hydroxyapatite (HA) [15-17]. Coating an implant surface with HA shortens the time needed to achieve adequate fixation strength, stability, and increases the strength of the bone-implant interface [18-20]. Traditionally, HA coatings are applied with a plasma spraying technique using high temperatures. However, plasma spraying may results in inconsistent coating depth within three-dimensional porous surfaces [21]. A low temperature precipitation technique called Peri-Apatite™ HA (PA) coating, has been developed whit the ability to coat all exposed surfaces of a three-dimensional porous structure.

The purpose of this study was to compare the micro-motion between a PA coated and a porous coated press-fit (PF) tibial component in a prospective randomized study, using RSA [1] as primary outcome.

Patients and Methods

Design

This study was a prospective randomised single-blind study of patients receiving a TKA for treatment of osteoarthritis of the knee. Patients from a single centre were prospectively randomised to receive either a Triathlon™ PA Knee or a Triathlon™ PF Knee System (Stryker, Mahwah, New Jersey, USA).

Participants

Randomisation was achieved using a sealed envelope technique. Three surgeons (MM, STL and CFN) were involved both in the selection and operation of the patients. Patients were blinded to the treatment allocated. Ethics Committee approval [D nr: 445/2005] was obtained from the local medical ethical committee prior to initiation of the study. Patients were considered for enrolment according to

their clinical findings and subject to gaining their written informed consent according to International Conference on Harmonisation Good Clinical Practice [ICH GCP] requirements. The inclusion criteria for selection to participate in the study are provided in table 1. The exclusion criteria are provided in table 2.

During the period of trial (2007-07-10-2008-02-14) 150 knee replacements were performed by MM, STL and CFN. 90 patients were excluded from the study by exclusion criteria, due to long travelling time for follow up, not wanting to participate or for not having met the inclusion criteria. 60 patients (26 men and 34 women) were enrolled in the study, with 30 patients randomised to each group. Three patients were excluded from the PF group intra-operatively; one patient received an implant which was not the implant randomised to the patient and one patient sustained an intraoperative tibial fissure fracture that precluded their further participation in the study. Another patient in the PF group was excluded due to not fulfilling the inclusion criteria. Therefore, 30 patients were included in the PA group and 27 patients in the PF group (Figure 1).

At the two year follow-up, 26 out of 30 patients were available for follow-up in the PA group; one patient had no initial RSA examination due to cerebral problems that required transfer to another hospital; two patients refused further participation in the study and one patient was unable to come due to pulmonary problems and did not have the energy to continue to participate in the study. In the PF group 24 out of 27 patients were available for follow-up at two years; two patients had required revision [both patient recovered from deep infection: one by a two séance revision and the other by soft tissue revision including change of insert] of their knee replacement. One patient was deceased (Figure 1).

Prosthesis

All patients received a chrome-cobalt femoral component. Patients in the PA group received a Triathlon™ tibial component with a porous coated chrome-cobalt sintered bead in-growth surface with an average of 20 μm thick PA coating of HA surrounding the sintered beads. To achieve the PA coating, the prostheses were immersed in a calcium phosphate bath at a regulated pH (7.4) and temperature (80°C). This resulted in pure single crystallised calcium deficient HA coating of all layers of the porous surface. Patients in the PF group received a Triathlon™ tibial component with a porous coated chrome-cobalt sintered bead in-growth surface. The Triathlon™ tibial trays in both groups had a delta-shaped stem and both knee replacement systems had a cruciate retaining (CR) design. No patellae were resurfaced in either group. The bony surface, of the femoral component for both groups, was identical to the coating for the tibial component.

Intervention

Each patient was given per-operative antibiotics (2 g cloxacillin iv. 15 to 45 minutes before surgery) and tranexamic acid (100 mg per kg administered iv). The surgeries were performed via a midline incision with a para-patellar medial entrance to the joint using appropriate guide instruments and according to the surgical-technique manual supplied with the knee system. Intraoperative, an intramedullary seated femoral guide was used and the distal cut was made. The four remaining femoral cuts were made with a four-in-one chamfer guide. The tibial guide was positioned extra medullary, pinned, and the proximal cut was made. The posterior cruciate ligament was retained. At the time of surgery eight tantalum markers (0.8 mm diameter; RSA Biomedical, Umeå, Sweden) were inserted into the proximal tibial metaphysis and five markers were inserted in the polyethylene tibial insert [4,22]. Postoperatively low molecular heparin (enoxaparin 100 mg/ml, 0.4 ml) for ten days, starting at six hours (four to eight) post-operatively) was used for thromboembolic prophylaxis. Mobilisation was similar for both groups and included full weight bearing.

Evaluation

The first RSA investigation was performed within three days of the operation after weight bearing had been achieved, and then at three months, one year and two years postoperatively. RSA was performed with the patient in a supine position with the knee of interest inside a calibration cage (Cage 10, RSA Biomedical, Umeå, Sweden). The 3D tibial component migration was measured using UmRSA software

Inclusion criteria
1. Patient suffering exclusively from osteoarthritis; Stage II-V [25]
2. Patient requiring knee prosthesis is suitable for the use of the Triathlon knee system
3. Patient understands the conditions of the study and is willing and able to comply with the scheduled post-operative clinical and radiographic evaluations and the prescribed rehabilitation.
4. Patient has signed the Ethics Committee approved Informed Consent Form prior to surgery.

Table 1: Inclusion criteria.

| Exclusion criteria |
|---|
| 1. Previous major knee surgery. |
| 2. Significant disabling problems from the muscular-skeletal system other than in the knees. |
| 3. Obese patients where obesity is severe enough to affect subject's ability to perform activities of daily living (body mass index, kg/m²: BMI ≥ 35). |
| 4. Patients with active or suspected infection. |
| 5. Patients with malignancy-active malignancy. |
| 6. Patients with severe osteoporosis, Paget's disease, renal osteodystrophy. |
| 7. Patients immunologically suppressed, or receiving steroids in excess of physiologic dose requirements. |
| 8. Patients with a neuromuscular or neurosensory deficit which would limit their ability to assess the performance of the device or which interferes with the patient's ability to limit weight bearing or places an extreme load on the implant during the healing period. |
| 9. Female patients planning a pregnancy during the course of the study. |
| 10. Patients with systemic or metabolic disorders leading to progressive bone deterioration. |
| 11. Patients who, as judged by the surgeon, are mentally incompetent or unlikely to be compliant with the prescribed post-operative routine and follow-up evaluation schedule. |
| 12. Patients with other severe concurrent joint involvements which can affect their outcome. |
| 13. Patients with other concurrent illnesses, which are likely to affect their outcome such as sickle cell anaemia, systemic lupus erythematosus or renal disease requiring dialysis. |
| 14. Patients under the protection of law (e.g. guardianship). |

Table 2: Exclusion criteria.
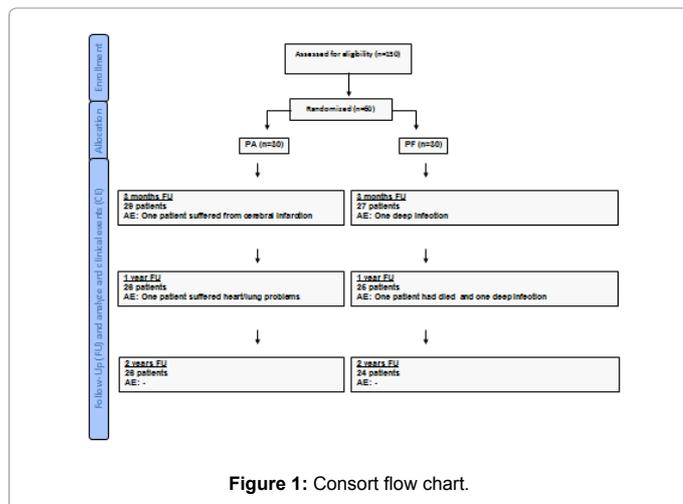
Figure 1: Consort flow chart.

(v6.0, RSA Biomedical, Umeå, Sweden).

The migration was described as segment motion [translation and rotation] of the geometric centre of the prosthetic markers and as the maximum total point motion (MTPM). The 3D motion of the prosthetic marker moving the most was used as a simplistic way to denote the magnitude of the micro-motion, and enabled the micro-motion between the tibial insert and the tibial bone to be described. Positive directions for translations along the orthogonal axes were: transverse (medial to lateral), longitudinal (caudal to cranial), and sagittal [posterior to anterior]. Positive directions for rotations about the coordinate axes were anterior tilt (transverse axis), internal rotation (longitudinal axis), and varus (sagittal axis). An increase in MTPM of more than 0.2 mm between the first and second year follow-up was considered as continuous migration [2] and these patients were classified as "at risk" of future implant loosening. In order to ensure accuracy of the measurements, stable fixation of the tantalum markers within the bone was essential. The upper limit for mean error (ME) of rigid body fitting (a measure of marker stability) was 0.2 mm, and the upper limit for condition number was 100. Tantalum markers were considered to be unstable if they moved more than 0.3 mm with respect to the other tantalum markers between examinations. Unstable markers were excluded from the analysis.

The repeatability of the RSA system was 0.12 mm, 0.21 mm, and 0.14 mm for x-,y-, and z-translations, and 0.12°, 0.11°, and 0.09° for x-, y-, and z-rotations. The repeatability of this investigation is described as 2xSD for all rotations and translations respectively [23].

Clinical Assessment

Clinical evaluation took place preoperatively and at three months, one year and two years postoperatively and consisted of the American Knee Society Score (AKSS) [24] and the Knee Injury and Osteoarthritis Outcome Score (KOOS) [25,26] questionnaires. The severity of osteoarthritis was graded according to the Ahlbäck classification [27]. The patients were evaluated by unbiased observers during the one and two year follow up period.

Statistical analysis

Sample size: From previous studies the migration during the first two years for total knee prostheses has been about 1.0 ± 0.5 mm (MTPM). If this migration will decrease by 50% to 0.5 ± 0.5 mm.

Considering an alpha level of 0.05 and a beta level of 0.20 (power ≈ 80%) this will require 17 cases in each group.

Continuous migration between the first and second year follow-up has been found in up to 50% of the cases. Suppose that an improvement will have to yield a decrease in continuous migration to 10% in order to be clinic relevant, an alpha level of 0.05 and beta level of 0.20 (power=80 %) would require 25 cases in each group.

Due to the risk of patient dropout, 30 patients were included in each group.

The statistical analyses were performed using SPSS statistics 17.0. All variables were considered to be continuous and were measured on an interval scale, except migratory pattern, which was proportional. The differences between the two treatment groups were evaluated with analysis of variance (ANOVA) for continuous variables at different time periods. Clinical scores were analysed using the analysis of covariance (ANCOVA) to compensate for different preoperative starting values. Continuous data which were not normally distributed were analysed by non-parametric ranking tests and proportional values were analysed by a chi-square test or a Fischer's exact test at low response frequencies. A p-value of 0.05 was used to determine statistical significance.

Results

Demographics

There were no difference between the two groups in terms of patient demographics and severity of osteoarthritis (all p-values>0.11) [Table 3].

RSA

The migration of the tibial components in millimetres is presented for each of the time point in table 4. Although the PA group demonstrated less longitudinal and sagittal migration, there were no differences in translation along the three coordinal axes at any time-point between the PA and the PF group. However, the PA group had less varus rotation at one year and two years (p=0.003 and p=0.014 respectively) and demonstrated a lower MTPM than the PF group at three months, one year and two years (p=0.011, p=0.001 and p<0.001 respectively). Whereas the MTPM for the PA group stabilised sometime within the first three months, the MTPM for the PF group stabilised after one year.

There were 8 out of 21 tibial trays in the standard PF group that demonstrated continuous migration between the first and second year follow-up, and there were 5 out of 21 tibial trays in the PA group that demonstrated continuous migration [Table 5].

Demographic data	PA Group	PF Group
Age (years ± SD)	65 ± 8	67 ± 7
Female:Male	18/12	15/12
Height (cm ± SD)	171 ± 9	171 ± 9
Weight (kg ± SD)	89 ± 16	85 ± 14
Mean body mass index (kg/m² ± SD)	30.4 ± 4.8	29.1 ± 4.2
Left:Right	15/15	16/11
Ahlbäcks Grade (n,%)		
I	0 *(0)*	0 *(0)*
II	7 *(23)*	12 *(44)*
III	22 *(73)*	13 *(48)*
IV	1 *(4)*	2 *(8)*

Table 3: Patient demographics.

	Preoperative		3 months		1 year		2 years	
	PA	PF	PA	PF	PA	PF	PA	PF
Knee Flexion (± SD)	117.3 ± 8.9	114.4 ± 12.7	115.2 ± 12.1	113.5 ± 14.2	125.6 ± 9.3	122.4 ± 7.7	125.9 ± 8.4	123.0 ± 8.1
Knee Extension (± SD)	4.2 ± 4.2	3.5 ± 4.3	0.7 ± 2.2	1.2 ± 2.6	0 ± 0	0.2 ± 1	0.4 ± 1.96	0.2 ± 1.0

Table 4: Knee flexion and extension angles.

RSA Assessment	3 months			1 year			2 years		
	Triathlon™ PA	Triathlon™ PF	p-value	Triathlon™ PA	Triathlon™ PF	p-value	Triathlon™ PA	Triathlon™ PF	p-value
Mean (95% CI) translation (mm)									
medial-lateral	-0.26 (0.48)	-0.36 (0.39)	0.895	-0.31 (0.54)	-0.64 (0.76)	0.787	-0.52 (0.37)	-0.48 (0.99)	0.939
caudal-cranial	0.14 (0.17)	-0.04 (0.33)	0.749	0.03 (0.17)	0.15 (0.42)	0.395	0.08 (0.25)	0.38 (0.57)	0.495
posterior-anterior	-0.01 (0.19)	-0.01 (0.25)	0.925	0.01 (0.23)	-0.62 (0.73)	0.197	-0.07 (0.28)	-0.49 (0.62)	0.455
Mean (95% CI) rotation (°)									
anterior tilt	-0.004 (0.13)	-0.05 (0.15)	0.356	-0.08 (0.18)	0.02 (0.25)	0.787	0.01 (0.24)	0.12 (0.29)	0.59
internal rotation	-0.34 (0.19)	-0.44 (0.13)	0.083	-0.18 (0.18)	-0.56 (0.19)	0.003	-0.21 (0.18)	-0.58 (0.23)	0.014
varus	-0.09 (0.16)	0.10 (0.20)	0.105	-0.09 (0.18)	0.14 (0.35)	0.246	-0.08 (0.16)	0.09 (0.43)	0.582
Mean (95% CI) MTPM (mm)	0.93 (0.28)	1.22 (0.19)	0.011	1.00 (0.29)	1.74 (0.48)	0.001	0.95 (0.28)	1.99 (0.62)	<0.001

Table 5: The mean translation and rotation of the tibial component measured by RSA at three months, one year and two years.
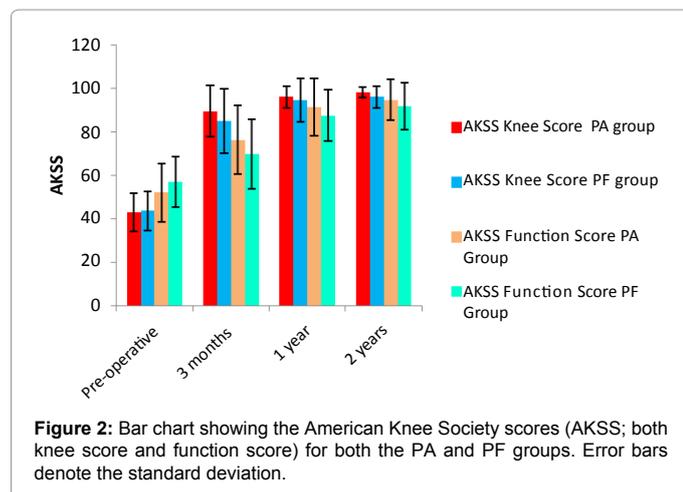

Figure 2: Bar chart showing the American Knee Society scores (AKSS; both knee score and function score) for both the PA and PF groups. Error bars denote the standard deviation.

Clinical assessment

Both groups showed an improvement in clinical outcome score postoperatively; however, there were no differences in the clinical outcome scores between the PA and PF group at any of the time-points [Table 6; Figure 2]. The range of motion (ROM) measured preoperatively and postoperatively at three months, one year and two years (within AKSS) are presented in table 4. There was no difference in ROM between the PA group and the PF group at any time-point.

Adverse events

In the PF group two patients suffered from deep infection and one patient got a tibial fissure per operatively. In the PA group one patient suffered from cerebral infarction and one from heart- and lung problem.

Discussion

Cemented fixation of the tibial components demonstrates smaller displacement in relation to non-cemented [with and without hydroxyapatite] after a follow-up of two years [11]. An initial period of implant migration as experienced in this study is to be expected for the tibial component of non-cemented knee replacements. In this study the migration of the PA coated implants had stabilised sometime within

three months of implantation and remained stable for the duration of follow-up.

Micro-motion continues until the underlying bone bed is of a suitable size and strength to support the implant. It is likely that the majority of migration occurred within the first six weeks, after which time the rate of migration decreased [8,21]. In this study, the MTPM for PA coated implants was lower than for the porous-coated implants, and the amount of subsidence and sagittal translation of the PA coated implants was, tendentiously, reduced. These findings support those reported by Voigt and Mosier in a meta-analysis of 14 trials that evaluated the benefits of HA coating of tibial components in TKA [28], in which the authors concluded that HA coating may enhance longer-term durability [as measured by MTPM analysis] in patients who are less than 70 years of age [28].

The presence of the bioactive HA coating is the most likely explanation for the more rapid stabilisation in the PA group. Bioactive coating of non-cemented implants is thought to promote early bone on growth and ingrowths into porous surfaces and enhance early fixation [29]. A number of studies have demonstrated that these benefits result in reduced implant migration within the first five years of implantation when compared to implants without HA coating [11,15,16,29-31]. There were a lower number of components at risk of loosening due to continuous migration in the PA group compared to the PF group. This finding has also been reported by Hansson et al. [21], in their study of the effects of PA coating. However, the proportion of implants that had continuous migration in the study by Hansson et al. [21], was higher than reported here, but could be related to difference in stem-design, for both the PA coated group and for the uncoated group. It may be possible that the design modifications that have occurred between the Duracon® and Triathlon™ knee replacement systems have improved the stability of the Triathlon™ knee system.

The higher number of continuously migrating components in the PF group in the present study has not translated into a higher revision rate for aseptic loosening, despite that two patient were revised because of deep infection. It will be interesting to follow these patients out to ten years to note if the predictive value, of continuous migration, given by Ryd et al. [2] has been applicable to this group. Resent discussion of phased introduction of new implants indicate, that the mean MTPM of the first year of FU could be used as an early detector of late mechanical loosening [32]. At one year mean MTPM [95% CI]

		Preoperative		3 months		1 year		2 years	
		PA	PF	PA	PF	PA	PF	PA	PF
KOOS	KOOS Mean pain score ± SD	38.9 ± 16.5	41.3 ± 17.4	71.9 ± 17.3	68.8 ±19.3	84.1 ± 14.2	80.8 ± 16.8	89.9 ± 11.7	91.7 ± 12.5
	KOOS Mean symptom score ± SD	48.4 ± 19.6	45.7 ± 20.6	64.9 ± 18.2	62.7 ± 17.1	81.4 ± 13.4	80.8 ± 11.25	85.9 ± 11.7	83.6 ± 14.8
	KOOS Mean ADL score ± SD	47.2 ± 17.1	45.1 ± 18.5	76.8 ± 13.5	71 ± 16.0	83.2 ± 13.5	79.96 ± 15.8	86.8 ± 11.99	86.6 ± 13.1
	KOOS Mean sports/recreation score ± SD	8.7 ± 10.3	12.4 ± 13.7	24.0 ± 22.2	26. 1 ± 21.0	38.9 ± 28. 4	32.6 ± 29.5	46.4 ± 27.3	41.4 ± 32.6
	KOOS Mean QOL score ± SD	23.1 ± 11.3	22.8 ± 14.1	58.1 ± 21.4	55.1 ± 20.7	65.3 ± 23.6	68.9 ± 21.0	73.9 ± 20.2	72.6 ± 18.5

Table 6: Clinical outcome scores according to the Knee Injury and Osteoarthritis Outcome Score (KOOS).

was 1.00 [0.29] for the PA- and 1.74 [0.48] for the PF-group. The limit for what is described as the first class group is MTPM<0.5 mm [32]. However if this limit is applicable to all types of knee prosthesis is argued and proposed for some to be lower and others even higher [1]. The upper limit and time frame for acceptable early migration seems to vary depending on several factors [type of implant, type of fixation and bone transplant [1]. The diagnosis of rheumatoid arthritis may also affect the fixation quality [33]. Loosening and wear are two important reasons for failure, which can be predicted with RSA, but failure of total joint replacements may have many other causes. Using the MTPM at one year, with considerations discussed by Kärrholm [1] in mind, the results of continuously migrating pattern (MTPM between year 1 and year 2), and the results from two meta-analysis regarding long term implant survival, implicating that non-cemented fixation may present a lower risk of future aseptic loosening [11,28]; the results of this study also indicates good long term outcome for both our groups.

Limitations and Strengths

Reasons for inclusion and exclusion in this series have been disclosed in table 1 and 2. Approximately 1/3 of the patients undergoing total knee arthroplasty during the period of this series were included, hence the risk for introducing potential bias.

The strength of this study is that both implant designs were screened under the same conditions in a randomised controlled trial.

In this study we used RSA as the primary outcome measurement and are aware of the limitations of the method. We used signed values in our calculations for segment translation and rotation [not for MTPM]. Since all migration along or around the cardinal axes can have either a positive or negative value (depending on the direction of the movement) using signed values leads to small mean values (close to zero) but rather large SD or confidence intervals. Compared to absolute values, where the size of the migration may have a bearing on future migration of fixation, we chose signed values as it gives clues to in what direction the implant migrates and gives an understanding of the mechanism of micro-motion/rotation for the studied implant. When absolute values are used this information of the mechanism is lost. MTPM is an absolute value without this more detailed information. As MTPM represent the value of the marker moving the most, it also has it´s limitation as to how to interpret the data. It could be different markers, moving the most, at different follow up times.

Conclusion

The short term RSA findings demonstrate that PA coating improves early implant stability

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