

Clinical results after ultrasound-guided intratissue percutaneous electrolysis (EPI[®]) and eccentric exercise in the treatment of patellar tendinopathy

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Abstract

Purpose To investigate the outcome of ultrasound (US)-guided intratissue percutaneous electrolysis (EPI[®]) and eccentric exercise in the treatment of patellar tendinopathy during a long-term follow-up.

Methods Forty patients with patellar tendinopathy were prospectively evaluated over a 10-year follow-up period. Pain and function were evaluated before treatment, at 3 months and at 2, 5 and 10 years using the Victorian Institute of Sport Assessment–Patella (VISA-P) score, the Tegner score and Blazina's classification. According to VISA-P score at baseline, patients were also dichotomized into Group 1 (<50 points) and Group 2 (≥50 points). There were 21 patients in Group 1 and 19 in Group 2. Patient satisfaction was measured according to the Roles and Maudsley score.

Results The VISA-P score improved globally by 41.2 points ($p < 0.01$) after a mean 4.1 procedures. In Group 1, VISA-P score improved from 33.1 ± 13 to 78.9 ± 14.4 at 3-month and to 88.8 ± 10.1 at 10-year follow-up ($p < 0.001$). In Group 2, VISA-P score improved from 69.3 ± 10.5 to 84.9 ± 9 at 3-month and to 96.0 ± 4.3 at 10-year follow-up ($p < 0.001$). After 10 years, 91.2 % of

the patients had a VISA-P score >80 points. The same level (80 % of patients) or the Tegner score at no more than one level lower (20 % of patients) was restored, and 97.5 % of the patients were satisfied with the procedure.

Conclusion Treatment with the US-guided EPI[®] technique and eccentric exercises in patellar tendinopathy resulted in a great improvement in knee function and a rapid return to the previous level of activity after few sessions. The procedure has proved to be safe with no recurrences on a long-term basis.

Level of evidence Therapeutic study, Level IV.

Keywords Intratissue percutaneous electrolysis · EPI · Eccentric exercises

Introduction

Patellar tendinopathy or jumper's knee is a frequent condition that most commonly affects the tendon's origin on the inferior pole of the patella [2, 4, 10]. Once considered an inflammatory condition, it is currently considered a degenerative process due to the presence of myxoid degeneration, the disruption of the collagen fibres and signs of hypoxia in tenocytes and resident macrophages [6, 17].

The overall prevalence of patellar tendinopathy is around 14 % in the sports population [3, 16], but may be as high as 40 % in highly demanding athletes [8]. The tendon's overuse in sports that involve running, jumping or rapid change in direction is considered the main risk factor for developing the said condition [16].

Current treatment options include eccentric training [15, 18, 29], open or arthroscopic surgery, extracorporeal shockwave therapy [25], ultrasound (US)-guided sclerosis [12], non-steroidal anti-inflammatory drugs, platelet-rich

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plasma injection [30] and aprotinin [1]. These studies have also suggested that, in general, patients with a worse functional status before treatment obtain inferior final outcomes. However, due to the limited evidence-based therapies, there are still several controversies regarding the real efficacy of these treatment modalities [1].

Intratissue percutaneous electrolysis (EPI[®]) treatment is a pioneering US-guided technique developed by one of the authors. It leads to a non-thermal electrochemical ablation through a cathodic flow directly at the clinical focus of degeneration. EPI[®] causes an organic reaction leading to a highly localized inflammation, exclusively at the region of treatment that conduces to a rapid regeneration of the injured tendon [26].

The present study provides the first analysis of the results of EPI[®] in the treatment of patellar tendinopathy at 10 years follow-up. This study could be clinically relevant given the lack of effective techniques in the treatment of patellar tendinopathy.

The aim of this study was to investigate the outcome of the US-guided EPI[®] technique in terms of pain, function and the return to the previous level of activity in patients with patellar tendinopathy. The mean follow-up of 10 years provides information on safety and the rate of recurrence. The main hypothesis was that the US-guided EPI[®] technique would quickly improve the outcome in patients with patellar tendinopathy and that this improvement would be maintained over a long period of time. The second hypothesis was that good outcomes would be obtained regardless of the initial degree of functional impairment. It was also hypothesized that the patients would be restored to their pre-injury activity level.

Materials and methods

From January 2002 to October 2002, 41 patients with patellar tendinopathy were included in the investigation. Demographic data and patient information (age, gender, affected and dominant side, kind of sport or activity level) were recorded.

The inclusion criteria were a history of patellar tendon pain, tenderness upon palpation, functional limitation directly related to the studied tendon and sonographic confirmation of tendon degeneration. A tendon injury located at the inferior pole of the patella was considered a requisite. Other inclusion criteria were more than 4 weeks of symptoms and an age of <60 years old. Patients were classified according to Blazina's scale [22]. Exclusion criteria were pain at the proximal pole of the patella (frequently included in jumper's knee), chronic articular disease, a concomitant knee pathology, contraindications to the EPI[®] technique and the concomitant administration of

certain drugs (at least 2 weeks before receiving treatment). The inclusion and exclusion criteria are summarized in Table 1.

Ultrasound examination

All the patients went through an exhaustive US examination of the tendon and adjacent structures using a high-resolution greyscale US (Fig. 1) with Doppler power and linear multi-frequency probe (6–15 MHz). The injured and the contralateral knees were studied in all patient. The US efficacy for the proper diagnosis of patellar tendinopathy was previously reported [11, 36, 37].

Intratissue percutaneous electrolysis (EPI[®]) protocol

The EPI[®] technique was applied using a specifically developed medically certified (Directive 93/42/EEC) device (EPI Advanced Medicine, Barcelona, Spain), which produces modulated galvanic electricity through the negative electrode cathodic flow. This is applied using a modified electrosurgical scalpel that uses acupuncture needles (0.3 mm in diameter) with different lengths. The intensity can be adjusted by changing the duration or the milliamps of the device. Conversely, the polarity of the machine is fixed (i.e. only the cathodic flow is usable). During the procedure, performed by the same experienced operator, the patients are supine so as to minimize any potential vagal reaction.

Isopropyl alcohol was used to prepare the skin despite the bacteriostatic action of the EPI[®] system. Polyvidone iodine was avoided to prevent a tattoo effect of the

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<60 years old	Chronic articular disease
History of patellar tendon pain >4 weeks	Concomitant knee pathology (e.g. cruciate ligament injury of meniscal tear)
Tenderness to palpation	Contraindications of EPI [®] technique (i.e. pregnancy, knee prosthesis, osteosynthesis, cardiac disease, malign tumour or coagulopathy)
Functional limitation directly related to the tendon injury	Concomitant administration of drug (i.e. fluoroquinolones, anticoagulants, corticosteroids or non-steroidal anti-inflammatory)
Sonographic confirmation of tendon degeneration	
Injury located at the inferior pole of the patella	
Blazina's classification \geq grade I	

Fig. 1 High-resolution colour Doppler ultrasound of patellar tendinopathy. **a** Longitudinal and **b** transversal views of the involved tendon showing a high degree of neovascularization before the EPI[®] treatment. The same patient 3 months after initiation of the EPI[®] procedures had a remarkable decrease in the vascularization of the patellar tendon clearly seen in these longitudinal **(c)** and transversal **(d)** views

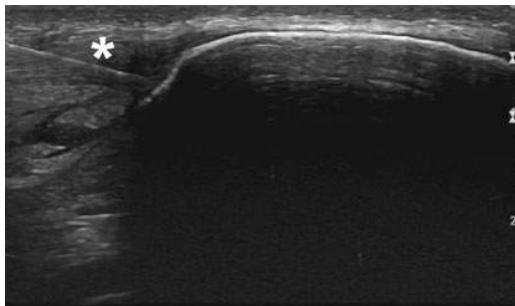
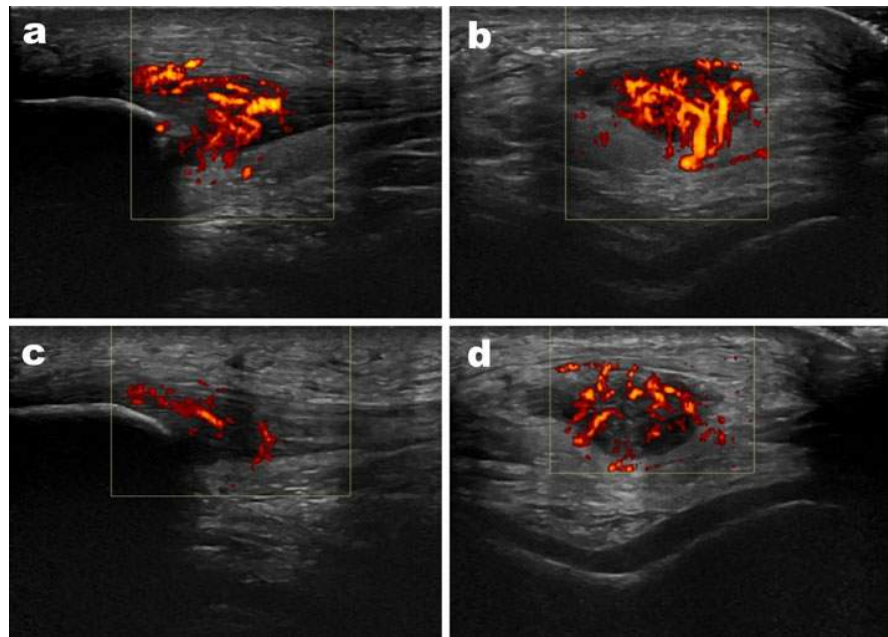


Fig. 2 Intratissue percutaneous electrolysis (EPI[®]) procedure. The 0.3-mm needle (Asterisks) is being guided by high-resolution greyscale ultrasound to puncture the injured region of the tendon

cathodic flow. Finally, three US-guided precise punctures at 3 mA (Fig. 2) were performed until a complete debridement of the treated area was obtained. The debridement was assessed with the sonographic images. After the first EPI[®] treatment, the patients underwent consecutive sessions of EPI[®] every 2 weeks and 2 weekly sessions of an eccentric exercise training using the resistance isoinertial leg-press machine (YoYo[™] Technology AB, Stockholm, Sweden). Eccentric exercises were performed in three sets of ten repetitions twice a week in order to obtain maturation of collagen fibres [24, 31]. Each repetition was performed with the concentric phase with both extremities, whereas the eccentric phase was only performed with the affected limb at a maximum of 60° of knee flexion.

Patients received US-guided EPI[®] treatment up to a maximum of ten sessions. The treatment finished either

when the patients were symptom free or if there was no improvement in terms of pain or function after those ten sessions.

Treatment evaluation

All the patients were evaluated before treatment and prospectively when their treatments were finished (at the third month), at 2-year, at 5-year and at 10-year follow-up.

The primary outcome measure was knee function using the Victorian Institute of Sport Assessment–Patella (VISA-P) score, a specific validated questionnaire to quantify pain and knee function and ability to play sport in patients with patellar tendinopathy [9, 34]. The VISA-P score ranged from a maximum of 100 in asymptomatic patients to the theoretical minimum of 0. The authors of the score suggested that a score between 80 and 100 points might be considered as the optimal outcome category. Functional evaluation was further assessed with Blazina's classification [22]. This classification categorizes the symptomatic patients as in *phase I* (pain only after activity), *phase II* (discomfort during activity), *phase III* (pain during activity that interferes with participation) and *phase IV* (complete tendon disruption). The Tegner score was also used to assess the influence of the treatment in terms of restoring the previous sports activity level. All the written questionnaires were personally filled out by all patient before treatment, at the end of the treatment (at 3-month) and at the 2-year follow-up. The questionnaires corresponding to the 5- and 10-year follow-up evaluations were all filled out through a telephone interview. Patient satisfaction was

measured according to the Roles and Maudsley score [23]. In this score, patients are classified as *Excellent* (no pain, full movement and full activity), *Good* (occasional discomfort, full movement and full activity), *Fair* (some discomfort after prolonged activity) or *Poor* (pain limiting activities).

All those patients that scored <50 points with the VISA-P questionnaire at baseline were denominated Group 1, whereas the remaining patients scoring equal to or higher than 50 points were denominated Group 2. This classification allows to display the results in different degrees of injury of the patellar tendon: more (VISA-P < 50 points) or less affected (VISA-P > 50 points).

The Clinical Research Ethics Committee of ICATME-Institut Universitari Dexeus, University of Barcelona, approved the study (09/06/0049). All the patients signed informed consent to participate in the study as well as for the evaluation and publication of their results.

Statistical analysis

Categorical variables are presented as number of cases and percentages. Continuous variables are presented as mean \pm SD (range). The relationships between categorical variables were described using contingency tables, and inference was studied using the chi-square test or Fisher's exact test. The relation between the VISA-P score and dichotomous variables was assessed using the Mann-Whitney test, showing the median value. Analysis of variance (ANOVA) was used to compare the evolution between groups. Statistical significance was set at 0.05 two-sided. Statistical analysis was performed using SPSS 19 (SPSS Inc., Chicago, IL, USA).

Results

One patient was lost during the first 3 months of follow-up. The remaining 40 patients were available at the 3-month and at the 2-year evaluations. At the 5-year evaluation, another three patients were lost (37 patients available, 90.2 % of the cases) and another three patients at the 10-year assessment (34 patients available, 82.9 % of the cases).

Patient description

Twenty-one patients (52.5 %) were included in Group 1 and the remaining 19 (47.5 %) in Group 2. Both groups were comparable in terms of age, gender, side and functional scores at baseline (Table 2). Sports involvement is summarized in Table 3. No relation (n.s.) between the injured tendon and the dominant extremity, the type of

sport, the age of the patient and gender, and the VISA-P values obtained after the treatments was observed.

The mean duration of symptoms prior to the treatment was 69.4 ± 65.6 weeks (range 4–288 weeks). The athletes were off sports activities due to their patellar tendinopathy for a mean time of 40.6 ± 50.9 weeks (range 0–192 weeks). Treatment duration averaged 7.5 ± 2.6 weeks (range 1–10 weeks), and the patients required a mean of 4.1 ± 2.6 EPI[®] procedures (range 1–10). According to Blazina's classification, one patient (2.5 %) was of stage I at baseline, seven patients (17.5 %) stage II and the remaining 32 patients (80 %) stage III. At the 3-month evaluation, once all the treatments were finished, five patients (12.5 %) were classified as of stage I and six patients (15 %) stage II. All the remaining 30 cases (72.5 %) were considered completely cured (less than Blazina's stage I). At the 2-year follow-up evaluation, 31 cases (77.5 %) were asymptomatic (less than Blazina's stage I) and nine (22.5 %) were in stage I. Analysis

Table 2 Patient characteristics at baseline

	Group 1 <i>n</i> = 21 (52.5 %)	Group 2 <i>n</i> = 19 (47.5 %)	<i>p</i> value
Age (years)			
Mean \pm SD	26.0 \pm 8.49	25.7 \pm 8.12	n.s.
Gender % (<i>n</i>)			
Male	81.0 (17)	94.7 (18)	n.s.
Female	19.0 (4)	5.3 (1)	
Dominant extremity % (<i>n</i>)			
Right	81.0 (17)	89.5 (17)	n.s.
Left	19.0 (4)	10.5 (2)	
Injured knee % (<i>n</i>)			
Right	38.1 (8)	15.8 (3)	n.s.
Left	47.6 (10)	68.4 (13)	
Bilateral	14.3 (3)	15.8 (3)	
Baseline VISA-P			
Mean \pm SD	32.5 \pm 12	69.5 \pm 10.05	<0.001

Values expressed as mean \pm SD or frequencies and percentages

Table 3 Patient sports involvement at baseline

	Series <i>n</i> = 40
Blazina's stage	
Median (range)	3 (2–3)
Sports type % (<i>n</i>)	
Soccer	60 (24)
Other	40 (16)
Sports level % (<i>n</i>)	
Professional (first division)	12.5 (5)
Semi-professional (second division or similar)	67.5 (27)
Recreational	20 (8)

Values expressed as mean \pm SD or frequencies and percentages

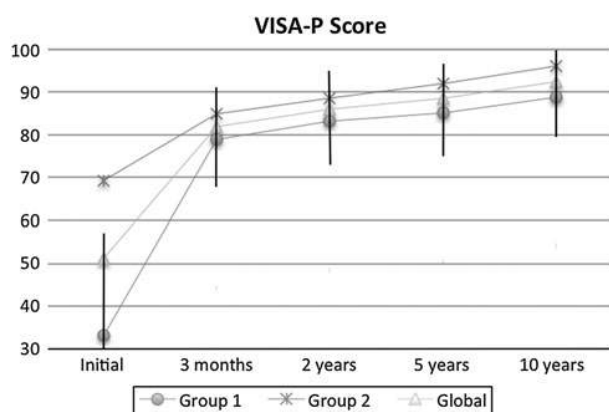


Fig. 3 Linear diagram of the mean Victorian Institute of Sport Assessment–Patella (VISA-P) scores for Group 1, Group 2 and all the patients (*Global*) at baseline (*Initial*), at 3 months and at 2, 5 and 10 years

of the patients using the Blazina’s classification remained unchanged throughout the remaining follow-up evaluations of the period studied (n.s.).

Clinical outcomes over time

The VISA-P (Fig. 3) and Tegner scores before treatment, at 3 months and at 2, 5 and 10 years of follow-up are summarized in Table 4. Group 1 improved by 45.8 points ($p < 0.001$) at 3 months to obtain a mean VISA-P score of 78.9 ± 14.4 . In Group 2, the mean improvement in VISA-P score at 3 months was 15.6 points at 3 months ($p < 0.001$). The Tegner level did not drop over the 10 years of the study period, and no differences between the intermediate evaluations (n.s.) were observed either.

According to the Roles and Maudsley score, patient satisfaction at 3 months of follow-up was considered *Excellent* in 32 cases (80 %), *Good* in seven cases (17.5 %) and *Fair* in one case (2.5 %). These values persisted without significant differences throughout the period studied. No recurrences, adverse episodes or any additional

modality of treatments were reported after the 10 years of follow-up.

At the 3-month follow-up evaluation, 32 (80 %) patients restored their previous activity level according to Tegner scale (n.s.). In eight patients (20 %), there was a decrease in only one single level on the same scale. These values were maintained over the remaining period studied (n.s.).

Discussion

Treatment with EPI[®] in combination with eccentric exercises has been shown to effectively improve the symptoms of patellar tendinopathy quickly and steadily for at least 10 years. It confirmed the first hypothesis. This improvement in patients that had different severities of VISA-P scores at baseline was equally obtained in terms of symptomatology, knee function and return to sports activity, which is also in concordance with the second hypothesis. The results observed in the first study reporting on the clinical use of EPI[®] are encouraging [26]. Its effects are based on a local and non-thermal electrochemical therapy that induces a localized short inflammatory response through an electrolytic reaction produced by a cathodic flow. Consequently, this causes an organic reaction leading to the regeneration of the injured tendon [26].

Conservative treatment was traditionally considered the first option of treatment of tendinopathies. Many different techniques were used [1, 8], such as modification of activity, eccentric physical training, patellar straps, cold and heat compression transfriction massage and stretching for quadriceps, hamstrings and patellar tendons. Despite some good results reported with eccentric programmes [18, 28], it is still unclear as to the more effective exercise protocol, its frequency, load and dosage. While Zwerver et al. [37], in a recent randomized clinical trial, concluded that no benefit came of extracorporeal high-energy shock-wave therapy during competition, Rompe et al. [25] reported, at 4-month follow-up, that eccentric loading

Table 4 Victorian Institute of Sport Assessment–Patella (VISA-P) values during follow-up

Time	VISA-P score			Tegner score		
	Group 1	Group 2	Global	Group 1	Group 2	Global
Baseline ($n = 40$)	33.1 (± 13)	69.3 (± 10.5)	51.2 (± 21.7)	8.1 (6–10)	7.8 (4–9)	7.9 (4–10)
3 months ($n = 40$)	78.9* (± 14.4)	84.9* (± 9)	81.9* (± 12.2)	7.7 (4–10)	7.6 (3–9)	7.7 (3–10)
2 years ($n = 40$)	83.2 (± 13.6)	88.6 (± 7.4)	85.9 (± 11.1)	8.1 (5–10)	7.7 (4–9)	7.8 (4–10)
5 years ($n = 37$)	85.2 (± 12.2)	91.9 (± 5.6)	88.6 (± 10)	7.9 (5–10)	7.6 (4–9)	7.8 (4–10)
10 years ($n = 34$)	88.8 (± 10.1)	96.0 (± 4.3)	92.4 (± 8.5)	7.7 (5–10)	7.3 (4–9)	7.5 (4–10)

Victorian Institute of Sport Assessment–Patella (VISA-P) values expressed as mean (\pm SD). Tegner values are expressed as median (range)

* $p < 0.001$. No statistically significant differences were observed in the results between any intermediate outcome measurements other than from baseline

alone was less effective when compared with a combination of eccentric loading and repetitive low-energy shock-wave treatment. Similarly, low-intensity US is not currently considered a reliable method for the treatment of patellar tendinopathy [14, 15, 35].

Different injection treatments for patellar tendinopathy have been proposed. While some studies on the effect of dry needling, autologous blood and high volume have been put forward as providing functional improvements, steroid treatment has shown a relapse of symptoms after few months, not to mention the deleterious effect on the tendon histology [32]. Recent investigations have observed slightly better outcomes after treatment with platelet-rich plasma injections in association with an eccentric training programme than an eccentric training programme alone in short-term studies [7, 30, 32]. Some authors had initially reported pain relief after sclerosing injections of polidocanol [10], but recent studies have shown contradictory results [33]. Hoksrud et al. reported their results with US-guided sclerosis of neovessels in 29 patients with 44 months of follow-up [12] and in 101 patients with 24 months of follow-up [13]. The patients needed several injections over 8 months of treatment, and only a moderate improvement in knee function was observed. One-third of their patients obtained a VISA-P score <50 points, and only few patients were completely cured. Conversely, in the present investigation with short- and long-term reported outcomes, even the patients with lowest VISA-P score (<50 points) at baseline significantly improved to around 80 points at 3 months and to around 90 points at 10 years. These final outcomes were comparable with those obtained by the patients with better VISA-P scores before treatment. This is of considerable relevance because the professional sports patients included in this series started from lower VISA-P values and they still obtained excellent scores. Overall, 80 % ($n = 32$) of the treated patients returned to the same level of sports activity at 3 months, and the remaining eight patients only decreased a single level in the Tegner score.

Regarding surgical treatment of patellar tendinopathy, some open [5, 21] and arthroscopic [5, 20, 27] techniques have also been recommended when conservative treatment fails. However, surgery usually provides unpredictable and inconsistent results [4, 15], which is often no more effective than an isolated eccentric exercise programme [2], and it does not allow the athletes to resume their previous sports at the same level, at least within the first year of treatment [19].

The main strengths of the current study are that, as far as we know, it is the first investigation reporting on any treatment modality for patellar tendinopathy over the course of 10 years. Few patients were lost during this long follow-up period. In addition, it is also the first study reporting on the clinical outcome using the EPI[®] technique

in the treatment of tendinopathy at long term follow-up. The promising results obtained with the EPI[®] procedure showed excellent functional results assessed with the VISA-P score as well as with the Blazina's classification in around 80 % of the patients at 3 months and over 90 % at 10 years. It also allowed a full recovery to the previous activity level in most patients. This outcome's improvement with the use of EPI[®] in the treatment of patellar tendinopathy was achieved after a short period of time (mean 7.5 weeks) and with a few number of treatment sessions (mean 4.1 EPI[®] treatments).

Besides the low sample size, one of the most relevant limitations of the current study is the lack of a control group. Comparison with a placebo-treated group of patients would have made for much stronger conclusions. However, most of our patients were professional or semi-professional athletes referred by other physicians after failure of conservative therapy. It seems highly unlikely that this sort of patients would be willing to accept placebo treatment for a long enough period. Another weakness might be that the combination of treatment with eccentric exercises might have positively affected the results attributed to the EPI[®] technique. Although this could more logically affect the results during the first months of follow-up, it does not seem that it should have had any influence in the long-term results. Regardless of the aforementioned limitations, this study provides the first analysis of the EPI[®] technique on the treatment of patellar tendinopathy, with promising results after a long follow-up period.

The clinical relevance of the reported results was that EPI[®] technique brought about a major improvement in pain and function in comparison with the so far known techniques and offers a good treatment option in patellar tendinopathy.

Conclusion

Treatment with the US-guided EPI[®] technique and eccentric exercises in patellar tendinopathy resulted in a great improvement in knee function and a rapid return to the previous level of activity after few sessions. The procedure has proved to be safe with no recurrences on a long-term basis.

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