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SINGLE-STAGE INTRAOPERATIVE APPLICATION OF AUTOLOGOUS ADIPOSE-DERIVED STROMAL VASCULAR FRACTION WITH PLATELET-RICH PLASMA IN DISTAL BICEPS TENDON REATTACHMENT: TECHNIQUE AND SAFETY

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Abstract: The paper describes how autologous adipose-derived stromal vascular fraction (SVF) is obtained and applied with platelet-rich plasma (PRP) during distal biceps tendon reattachment with an adjustable-loop oval cortical button, and assesses the safety of this approach. Of 30 patients with this fixation, 14 also received SVF with PRP. The product was ready 20–30 min after fat harvest. No clinically significant complications occurred; minor events were noted in 1 of 14 patients with SVF and 2 of 16 without it ($p = 1.000$). Leukocyte counts remained normal, and C-reactive protein and erythrocyte sedimentation rate were similar in the two subgroups at every visit.

Keywords: Distal biceps tendon, stromal vascular fraction, platelet-rich plasma, adipose tissue, cell therapy, tendon-to-bone healing, safety.

Introduction. The durability of distal biceps tendon reattachment ultimately depends on tendon-to-bone healing, and the biological conditions for it are unfavourable: spontaneous tendon ruptures are almost always preceded by degenerative changes [1], and the distal biceps tendon contains a zone of poor blood supply [2]. Biological stimulation of tendon-to-bone integration is therefore a logical complement to mechanical fixation.

The stromal vascular fraction (SVF) of adipose tissue, a heterogeneous cell population that includes mesenchymal stromal cells, can be isolated from lipoaspirate during surgery without cell culture. In vitro, SVF cells express growth factors and chemokines involved in tendon repair, and adipose-derived stromal cells exert a trophic effect on tenocytes [3]; in rabbits, local SVF application after rotator cuff repair produced a four-layer tendon–bone junction resembling the normal enthesis and higher repair strength [4]. A systematic review regarded adipose-derived stromal cells and SVF as safe in tendinopathy and tendon injury, although evidence of their efficacy remains limited [5]. Platelet-rich plasma (PRP) serves as an autologous vehicle that maintains cell viability and, once activated, forms a fibrin scaffold retaining the cells at the injection site [6]. Apart from our earlier report [7], we found no clinical studies of SVF in distal biceps tendon repair.

Aim. To describe single-stage intraoperative preparation and application of autologous SVF with PRP in distal biceps tendon reattachment and to evaluate its local and systemic safety.

Materials and methods. The analysis included 30 patients with a complete or high-grade partial tear of the distal biceps tendon not older than 7 days, operated on at the Zaporizhzhia Regional Clinical Hospital (trauma department) in 2019–2025 through a single anterior incision with an oval cortical button whose loop length was adjusted intraoperatively [8]. After discussing benefits and risks, 14 patients chose additional SVF with PRP, and 16 were operated on without it. The subgroups were comparable with respect to the injured side, whereas their sex and age differed: women predominated among patients who received SVF (13 of 14 vs 1 of 16; $p<0.001$), and these patients were older (52.0 ± 12.3 vs 46.2 ± 9.2 years; $p = 0.036$). All patients gave informed consent, and the study complied with the Declaration of Helsinki.

Immediately before or at the start of the operation, the donor site on the anterior abdominal wall was infiltrated with 100 ml of 0.9 % sodium chloride solution containing 5 ml of 2 % lidocaine and 0.05 mg of epinephrine, and lipoaspirate was obtained by microliposuction through a small puncture with the

Microlyzer SVF Kit manufactured by T-Biotechnology Ltd. (Turkey). The material was spun in sterile tubes at 2400 rpm for 5 min; the middle layer was passed through a 100 μm filter for mechanical fragmentation and centrifuged again, and the lowest fraction (SVF) was collected into a 5 ml syringe. PRP was obtained from the patient's venous blood (20–30 ml with sodium citrate) by two-step centrifugation, a soft spin to separate the platelet-rich plasma being followed by a hard spin to concentrate the platelets; 2–4 ml of it was added to the SVF immediately before use. After the button had been fixed, the mixture was delivered into the stump of the tendon and into the zone where it was attached to the radial tuberosity. Cell phenotyping of the product was not performed. Rehabilitation was identical: a sling for 2 weeks, then 2 weeks of careful pain-free passive exercises and gradual expansion of the motor regimen.

Safety was judged by wound healing, local complications and systemic inflammation markers: complete blood count with leukocyte differential, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) on day 3, at 2 and 6 weeks and at 3 months; pain (visual analogue scale, VAS), the Disabilities of the Arm, Shoulder and Hand (DASH) score and active range of motion were assessed at the same visits. CRP and ESR (M ± SD) were compared using Student's t-test or, if the Shapiro–Wilk test indicated a non-normal distribution, the Mann–Whitney U test; VAS and DASH scores (Me (Q25; Q75)) were analysed with the Mann–Whitney U test and event rates with Fisher's exact test ($p < 0.05$).

Results and discussion. In all 14 patients, the cell product was prepared in the same operating room without logistic difficulties; the cycle from fat harvest to a ready product took 20–30 min, so the SVF was available as soon as the mechanical reattachment had been completed.

Primary wound healing was achieved in every patient, and none of the 30 patients had a clinically significant complication (repeated rupture, heterotopic bone formation limiting movement, persistent posterior interosseous neuropathy or infection). Minor events (transient paraesthesia in the territory of the lateral antebrachial cutaneous nerve in one patient of each subgroup and minimal asymptomatic heterotopic ossification in one patient without SVF) were recorded in 1

of 14 patients (7.1 %) with SVF and in 2 of 16 (12.5 %) without it (p = 1.000; Table 1).

Table 1

Safety indicators in patients operated on with and without SVF

Indicator	SVF with PRP (n = 14)	Without SVF (n = 16)	p
Local events, n (%)			
transient paraesthesia (lateral antebrachial cutaneous nerve)	1 (7.1)	1 (6.3)	–
minimal asymptomatic heterotopic ossification	0	1 (6.3)	–
patients with any event	1 (7.1)	2 (12.5)	1.000
CRP, mg/l, M ± SD			
day 3	50.0 ± 5.2	50.1 ± 2.5	0.966
2 weeks	16.6 ± 2.4	18.3 ± 2.3	0.059
6 weeks	6.0 ± 1.6	7.0 ± 1.3	0.068
3 months	2.3 ± 1.0	2.5 ± 1.0	0.554
ESR, mm/h, M ± SD			
day 3	24.9 ± 3.9	24.5 ± 4.4	0.782
2 weeks	14.6 ± 3.4	15.0 ± 4.0	0.758
6 weeks	6.5 ± 1.7	5.8 ± 1.6	0.251
3 months	3.6 ± 1.5	4.3 ± 1.6	0.207

Note. p: Fisher's exact test (patients with any event); Student's t-test for normally distributed data, otherwise the Mann–Whitney U test (CRP, ESR); –: not compared.

The postoperative rise in leukocyte count stayed within the reference range in all patients, without a left shift, and no clinical signs of a systemic inflammatory response were observed. CRP and ESR peaked on day 3, fell markedly by 6 weeks and had normalized by 3 months in both subgroups, without significant differences between them; at 2 and 6 weeks, CRP was even slightly (non-significantly) lower after SVF application.

Clinical recovery after SVF application was not worse than without it. At 2

weeks, the SVF subgroup had less pain (median VAS 5 (5; 5) points with SVF and 5.5 (5; 6) points without it; p = 0.001), the DASH score was lower at 2 weeks (p=0.026) and 6 weeks (p = 0.029), and forearm rotation, mainly pronation, recovered faster during the first 6 weeks; by 3 months, the subgroups no longer differed. Given the sex and age imbalance and the co-administration of biologically active PRP, these differences cannot be attributed to SVF alone.

The absence of additional reactions agrees with the safety of adipose-derived cell products in tendon pathology reported in a systematic review [5] and with our earlier observations [7]. The technique is simple, requires no substantial extra costs and suits routine use. The early clinical benefit is consistent with the trophic action of SVF shown experimentally [3; 4]. Limitations are the non-randomized allocation, small subgroups (detectable effect size, Cohen's d ≥ 1.06), the open design, the lack of cell characterization and the 3-month follow-up.

Conclusions.

1. Autologous SVF can be harvested, isolated and combined with PRP within the same operation as distal biceps tendon reattachment; the procedure takes 20-30 min.

2. SVF with PRP was not accompanied by clinically significant complications or by more minor events (1 of 14 vs 2 of 16 patients; p = 1.000) and did not intensify the systemic inflammatory response (leukocyte count, CRP, ESR).

3. Early recovery after SVF with PRP was at least as good as after fixation alone and faster at 2–6 weeks; given the sex and age imbalance and the co-administration of PRP, the contribution of SVF itself requires verification in randomized trials.

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