Journal of Surgery
Weninger P. J Surg 8: 1914
www.doi.org/10.29011/2575-9760.001914
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Research Article

Joint Preservation in Patients with Grade-IV Osteo-Arthritis of The Knee – 12-Months Results after A Multimodal Approach Using Radiofrequency Ablation and Platelet-Rich-Plasma Supercharged Stem Cell-Rich Fat Graft in 42 Consecutive Patients

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Citation: Weninger P (2023) Joint Preservation in Patients with Grade-IV Osteo-Arthritis of The Knee – 12-Months Results after A Multimodal Approach Using Radiofrequency Ablation and Platelet-Rich-Plasma Supercharged Stem Cell-Rich Fat Graft in 42 Consecutive Patients. J Surg 8: 1914 DOI: 10.29011/2575-9760.001914

Received Date: 13 October, 2023; **Accepted Date:** 16 October, 2023; **Published Date:** 18 October, 2023

Introduction

Osteo-Arthritis (OA) of the knee is a painful, progressive and disabling disease that inflicts more than 86 million people worldwide with an incidence of 203 per 10,000 (95% CI, 106-331) [1-3]. It is characterized by chronic pain, swelling and impaired knee function leading not only to high pressure for inflicted individuals but also resulting in severe socio-economic consequences and loss of productivity [4]. OA of the knee is associated to certain risk factors such as age, weight, trauma or inflammatory and rheumatological diseases causing subsequent joint destruction [5]. It is not curable and to date the commonly accepted treatment is Knee Arthroplasty (KA) in the advanced stage of the disease, however, which is associated with substantial health costs [6,7]. Furthermore, KA, as every invasive surgical procedure, has its own risk profile with possible complications such as bleeding, need for blood components, infection, thrombo-embolic events or nerve damage [8-10]. Also, there is a relatively high number of patients that complain of persisting pain or limited range of motion after KA or even describe it as worse when compared to the per-operative situation [11,12]. That is why some authors rather prefer non-operative treatment of OA [13-15]. Classical treatment options are oral pain killers, crystalloid cortisone or intra-articular hyaluronic acid [16,17]. Today, ortho-biologic treatments are emerging and regenerative strategies have been described repeatedly. Those include intra-articular administration of platelet-rich plasma, adipose derived or bone marrow derived stem cells, use of stromal vascular fraction, micro-fat injections or combinations [18-20]. Also, pain reduction by using selective denervation of the knee joint was described by Dellon et al. as possible treatment option [21]. This resulted in more sophisticated treatment protocols by using minimally-invasive Radiofrequency (RF) ablation for OA treatment [22,23]. The present paper presents our approach in order to treat grade-IV OA of the knee using a regenerative approach with Adipose-Derived Stem Cell (ASC) -rich fat graft (liparthroplasty) and selective minimally-invasive RF ablation.

Material and Methods

We enclosed forty-two consecutive patients (mean age 68.4; range 49-96) that presented to Avancell Medical for treatment of grade-IV cartilage defects and severe pain resulting from knee OA. All patients were already scheduled for total KA by other surgeons but refused or came for second opinions. All patients had MRI scans not older than three months. There were 31 male and 11 female individuals, all of them with grade IV OA in ³ 2 compartments (medial or lateral femoro-tibial, patella-femoral). All patients reported significant pain according to the visual analogue scale >7 (mean 8.2). All patients underwent the same treatment protocol:

Patients were consented for liposuction and knee liparthroplasty [24] and for selective radiofrequency ablation (Coolief, Avanos Medical) of the sensory branches of the genicular nerves. Patients were placed and draped in supine position. First, local anesthesia was applied to the four sensory branches of the genicular nerves (at each site 10mL Lidocaine 2% with epinephrine 1:10.000). After waiting for ten minutes, the nerve branches were identified by ultrasound (Clarius HD, Canada). Then, the electrodes were placed on the four sensory branch locations. Subsequently, all four sensory branches were treated by cooled radiofrequency with maximum 63° Celsius, 100 Ohm impedance and 7 Watt for two minutes and thirty seconds in each of the four locations (Figure 1).

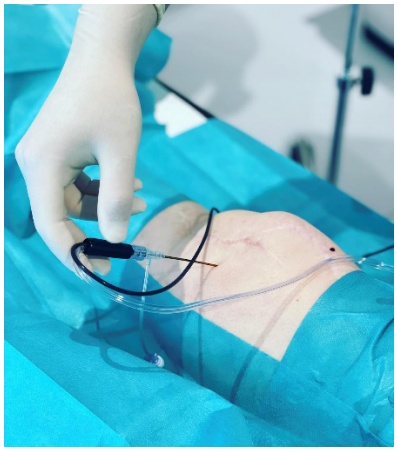

Figure 1: RF ablation electrode placed at the medial genicular nerve.

After radiofrequency ablation, the left abdominal region was prepared and draped for liposuction. Local anesthesia (1% lidocaine with epinephrine 1:1000) was used to numb the area. A tumescent solution (250 mL of saline solution, 1 mL of 1:200,000 adrenalin, and 600 mg of lidocaine, 8.4% sodium-bicarbonate) was inserted over a stab incision with a 100mL syringe. After fifteen minutes of waiting, liposuction was performed manually with a 20mL syringe with Luer-Lock and a 3mm cannula (Tulip Medical, USA). The cannula was inserted into the subcutaneous fat and by aspirating the syringe a vacuum was obtained. Liposuction then was performed by back-and-forth motions of the cannula, oriented parallel to the underlying fascia. Meanwhile, the non-dominant hand applied pressure to the abdominal wall ensuring depth and direction of the cannula (Figure 2).

Figure 2: Manual liposuction in the left lower abdominal quadrant.

Routinely, four 20mL syringes were filled with lipo-aspirate. The fat tissue was separated from fluids and oils using the decanting method without the need for being centrifuged Therefore, the syringes were placed upright and after few minutes the lipoaspirate separated. The fluid layer then was decanted by disposing it out of the syringe Next, the fat was mechanically homogenized with two syringes (shuffling method, Figure 3): One fat-containing syringe was connected to a second, empty syringe by a three-way valve. The fat was shuffled by transferring the content of one syringe to the other one 10 times, thus creating a refined fat graft. Meanwhile 15 mL of peripheral venous blood were drawn from the patients' cubital vein with the double-chamber syringe (Arthrex, Naples, US). This sample of venous full-blood was then centrifuged in a standard centrifuge (Rotofix 32 A, Hettich, Germany) with 1500 rounds for 5 minutes. The PRP-fraction was then inserted into the smaller of the two syringe chambers. The cellular whole blood fraction was then dismissed. The PRP fraction was then added to the fat graft. If two knees were treated, two double syringes were used to create PRP. A single-use 20-gauge needle was used to inject 10 mL of the combined PRP/fat graft into the knee joint. The knee joint was cycled afterwards. After the procedure, plasters were applied to all puncture wounds. Patients was recommended to use crutches for three days. They were advised to avoid stop-and-go sports for four weeks. Patients were followed-up after twelve months at least (12.0-14.4 months). We evaluated VAS, range of motion and the Knee Injury and Osteoarthritis Outcome Score (KOOS). Statistical analysis was performed by using SPSS (SPSS, USA). Statistical significance level was set at $p < 0.05$.

Figure 3: Shuffling method with two syringes to homogenize the fat graft.

Results

There were no complications or any adverse effects after liposuction, fat injection or radiofrequency ablation. Four patients had mild hematoma at the liposuction site. Two patients had quadriceps weakness that has resolved the next day. Twenty-three patients had minimal or mild effusion for some days.

VAS

Mean pre-interventional VAS was 8.2. No patient reported pain increase after the intervention. Two patients reported persisting pain at same level compared to pre-intervention. Forty patients reported significant pain reduction. In total, mean VAS was significantly reduced from 8.2 to 2.4 (range 0.0-3.5; p <0.05) (Figure 1).

ROM

Mean pre-interventional ROM was 0-2-125. No patient showed decreased ROM. In eight patients, ROM was similar to the pre-interventional ROM. In 34 patients, ROM increased. Mean post-interventional ROM was 2-0-145.

KOOS

All but two out of forty-two patients reported significantly improved KOOS values in all KOOS subgroups. Table 1 shows the KOOS values for each KOOS subgroups. Figure 4-9 shows all the KOOS subtypes before and after intervention.

	Before intervention	After intervention
KOOS Pain	43.2	82.0 (p <0.05)
KOOS Symptoms	42.2	82.4 (p <0.05)
KOOS Activities of Daily Living	37.6	80.6 (p <0.05)
KOOS Sports Recreation	35.6	81.4 (p < 0.05)
KOOS Quality of Life	34.4	79.9 (p <0.05)
Total KOOS	38.6	81.3 (p <0.05)

Table 1: Improvement of KOOS values in all subtypes and overall KOOS.

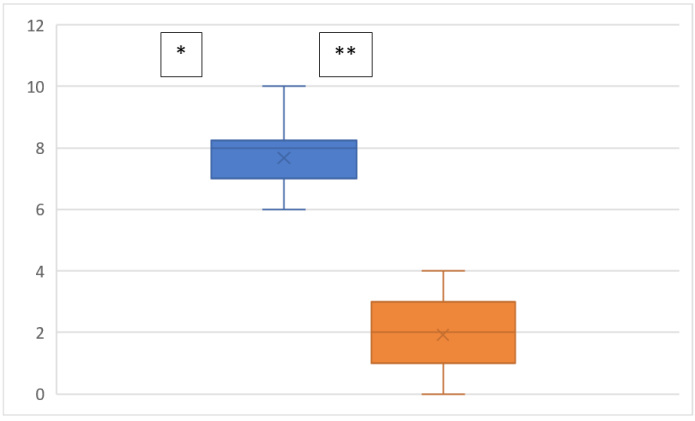

Figure 4: VAS *before and **after intervention.

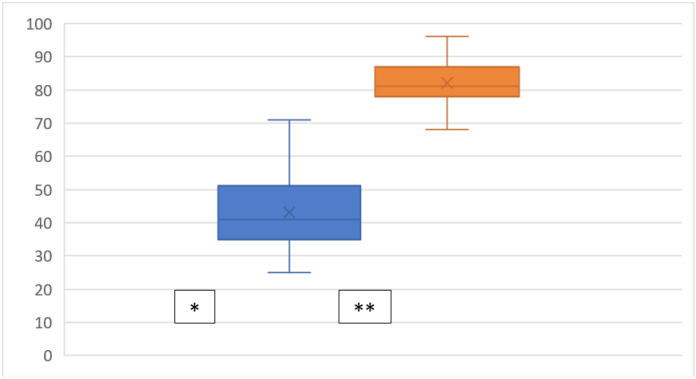

Figure 5: KOOS Pain *before and **after intervention.

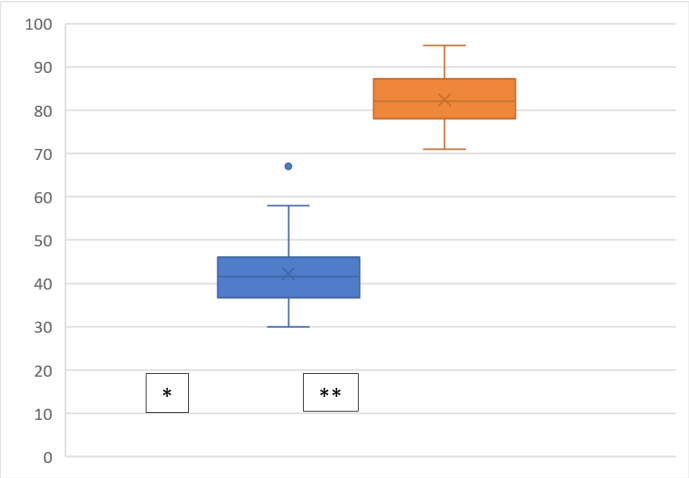

Figure 6: KOOS Symptoms *before and **after intervention.

Figure 7: KOOS Activities of Daily Living *before and **after intervention.

Figure 8: KOOS Sports Recreation *before and **after intervention.

Figure 9: KOOS Quality of Life *before and **after intervention.

Discussion

The described technique in order to treat severe pain in patients with grade IV OA of the knee has a success rate of 95.2 per cent (40/42). We showed a relatively simple and effective treatment option for patients with OA of the knee. To the best of our knowledge, this is the first study reporting clinical results in patients undergoing liparthoplasty and RF ablation. The herein used technique for harvesting and further for injection of stem cell-rich abdominal fat has been described recently by Weninger et al. [24]. Using the VAS and KOOS as valid outcome tools has been shown previously [25]. The intra-articular administration of stem cell-rich fat graft for orthopedic indications has been recently pointed out in numerous studies [25-28]. Froschauer at et al. were the first authors describing the technique of liparthroplasty in a series of patients with carpo-metacarpal arthritis [27]. In a recently published case series, the same author reported significant improved disabilities of function of the arm, shoulder, and hand (DASH) score after a median five-years follow-up [29]. Jo et al. reported encouraging results after intra-articular injection of adipose-derived mesenchymal stem cells for the treatment of osteo-arthritis of the knee [30]. They concluded this method to be as safe and effective treatment option. The same results were described by Lee et al. who performed a randomized, placebo—controlled clinical trial using ASCs and a six-months follow-up period [31]. In accordance to our study, the authors did not find any adverse events or complications in their patients. Furthermore, they evaluated Magnetic Resonance Imaging (MRI) scans of the verum – and of the falsum group and found increased cartilage defects in the control-group. Lapuente et al. showed clinical improvement of severe knee OA which they were able to correlate to ultrasound findings and biochemical parameters by showing a marked decrease of pro-inflammatory molecules and a significant increase of anabolic and anti-inflammatory parameters [26]. According to their results they concluded the adipose-derived Stromal Vascular Fraction (SVF) as effective during one year. This might be caused by a cascade of molecular and structural events that, through complex interactions between the infrapatellar fat pad and SVF, re-educating the intra-articular fatty tissue towards a homeostatic, protective, and anti-inflammatory function, which will ultimately promote the restructuring and regeneration of damaged tissues. Also from other publications, we know the paracrine effect of fat grafts modifying the intraarticular biochemical molecules and cytokines in a more chondro-protective direction [32,33].

The role of radiofrequency ablation to capture the genicular nerves in patients with knee OA was described repeatedly. In a systematic review, Gupta et al. reviewed seventeen publications on the efficacy and safety of RF ablation (22). The authors concluded that these studies showed promising results for the treatment of severe knee pain . Furthermore, they stated that RF ablation can offer substantial clinical and functional benefit to patients with chronic knee pain due to OA or after total KA. This is in accordance to Erdem et al. who described ultrasound-guided RF ablation as safe and minimally invasive procedure that significantly alleviates pain and disability in patients with severe degenerative disease or with previous knee arthroplasty [34]. Compared to KA, the here described technique is a minimally-invasive and safe one that showed no significant complications. Its efficacy has become evident and for us it is a suitable alternative to KA especially when considering the risk profile of KA.

Also it needs to be pointed out that it might be an alternative to KA when considering the worldwide healthcare problems due to the COV-SARS-pandemic during the last years which lead to cancellation of operations and long waiting lists. The herein described protocol is suited for in-office use and does not need the hospital setup with all its infrastructure and personnel and in fact is a method to relieve the hospitals. Therefore, we choose our protocol as treatment of choice in patients with any kind of cartilage damage without clinical or MRI-verified blockades caused by meniscus tears or loose bodies. Especially in patients who are relatively young and not ready for KA and elder patients with co-morbidities it can be a reliable alternative to KA.

Weakness of The Study

The present study was designed as observational study and not as prospective or randomized, or placebo-controlled trial which one could interpret as weakness, Furthermore, no MR imaging was used to monitor cartilage volume or defect sizes to provide serious and reliable information if cartilage volume changed. Also another weakness has to be pointed out: In an interesting study by Saltzman et al., the authors showed that the administration of saline into the knee joint yields a statistically and clinically meaningful improvement of patient-reported outcome up to six months after the injection in patients with knee OA [35]. Therefore, one has to be cautious when interpreting the results and findings. We combined two interventions in our protocol so we cannot reliably attribute the effect to a certain intervention. Even if improvement of symptoms was evident after 12 months, we, so far, cannot provide any data on the long-term course.

Conclusion

The described protocol is a safe and effective treatment option for patients with severe knee pain due to grade IV OA. It also seems to be a reliable alternative to KA in these patients twelve months after the intervention. Further clinical studies are necessary to proof this concept.

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