The use of activated Platelet Rich Plasma (PRP) in human autologous fat transfer.

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To objectify improvements in local skin quality and graft take by the addition of PRP.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON39492

Source
ToetsingOnline

Brief title
The use of Platelet Rich Plasma (PRP) in human autologous fat transfer.

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
atrophy, dermal improvement., loss of volume

Research involving
Human

Sponsors and support

Primary sponsor: Bergman Clinics
Source(s) of monetary or material Support: Bergman Clinics,BioMet

Intervention

Keyword: Dermal improvement, Graft survival, Lipofilling, Platelet rich plasma

Outcome measures

Primary outcome

Postoperative skin quality measured with a Multi Probe Adapter system (Courage Khanza Colone Germany) containing several skin measurement probes (Maxameter mx18: Assessing melanin content and erythema level, Tewameter TM300: Skin barrier function and transepidermal waterloss, Cutometer MPA580: Mechanical parameters of the skin) on predetermined fixed positions in the face on predetermined times .

Secondary outcome

Scores derived from standardized photographic assessment by two panels (plastic surgeons and layperons). The method used for assessment is based on methods described by Moolenburg and Strasser. Output parameter is a visual analogue score ranging from 0 (very poor facial volume) to 10 (excellent facial volume), and for skin quality 0 (pour skin quality) to 10 (excellent skin quality). Standardized photos will be taken at the follow-up visits.

Results of the patient questionnaire with endpoints: number of complications, Return to work/Return to social activities without masking in days. Patient evaluation of their own appearance using a visual analogue scale ranging from 0 (very dissatisfied) to 10 (most satisfied).

Study description

Background summary

Soft tissue augmentation by the means of lipofilling is nowadays a frequently used technique in all forms of plastic surgery. In aesthetic facial surgery it has shown to increase the rejuvenating effect, in reconstructive surgery it has earned its place in the correction of soft tissue defects and athropy.
Post-operative loss of volume of the transplanted fat remains an uncertain factor in the procedure. In current literature, there are three main hypotheses on etiology of postoperative decrease in the graft volume; 1: the viability of the injected fat cells 2: impaired graft revascularization at the target site 3: the degree of fibrosis in the target area. Mentioned factors have limited the application of (large) volume lipotransfer.

Positive effects of lipofilling on skin quality have been reported. Coleman observed softening of wrinkles, decreasing pore size and pigmentation improvements on graft sites. Possible mechanisms of the claimed regenerative properties of the lipograft are explained by the high number of adipose derived stem cells. Although frequently described in literature, no objective results have been published to this date.

In this prospective study we investigate new methods in preventing postoperative volume loss by the addition of Platelet Rich Plasma (PRP), derived from the patients own blood, to the injected fat graft. The added PRP contains a wide range of growth factors for instance: Epidermal growth factor (EGF), Platelet derived growth factor (PDGF-AA), Transforming growth factor (TGF-B1, TGF-B2) ,Fibroblast growth factor (FGF) and Vascular endothelial growth factor (VEGF).
All previously mentioned factors have shown to play a key role in tissue regeneration after tissue damage. Especially VEGF is of great interest with the ability to promote neo-angiogenesis in the graft, and thus, in theory, reducing fat necrosis and seroma formation.

Current, scientifically validated, use of PRP include treatment of chronic and soft tissue ulcerations, applications in the periodontal and oral surgery, maxillofacial surgery, orthopaedic and trauma surgery, cosmetic and plastic surgery, spinal surgery, heart bypass surgery, and burns. In all mentioned applications, PRP showed to have a positive influence on the tissue recovery and regeneration. Local PRP application in damaged animal and human skin showed to have regenerative properties. Structural changes to the dermal layer were observed in biopsies.

In this prospective, randomized clinical trial, lipofilling of the midface with PRP is compared with lipofilling of the midface without PRP. The main objective of this study is to investigate the effect of the addition of PRP to the autologous fat transfer on local skin quality improvement, graft survival, and recovery after the procedure.

The synergy achieved by lipofilling with PRP may hold many future applications in both reconstructive and aesthetic plastic surgery. Current limitation of

lipofilling, especially large volume lipo transfer (allowing reconstruction in one procedure in stead of multiple with smaller volumes) and lipofilling in pour vascularised tissue (eg. fibrosis after radiation therapy) may be countered by the addition of PRP. Furthermore, the suggested local skin improvements could be used in scar revisions and burn treatment in the future, bypassing invasive surgery.

Study objective

To objectify improvements in local skin quality and graft take by the addition of PRP.

Study design

Randomized controlled trial, 16 vs 16 patients

Intervention

The Coleman technique for fat harvesting and injection is employed but refined by utilizing a smaller, custom-made cannula for harvesting (inner diameter, 1.3 mm). The abdomen and upper legs are donor sites. Approximately two to three times more fat is harvested than the estimated amount required for the procedure. Fat is centrifuged for three minutes at the maximum speed of 3000 revolutions per minute after which the oil layer (top) and serum/infiltrate layer (bottom) are drained away, preserving the preadipocyte-rich pellet. Fat injection is performed in 1-mm aliquots with a short, curved Coleman cannula. Between 13 and 23 mL of fat is injected into the deep subcutaneous plane of each side of the face, except for the lower lid/tear trough region (where the injection is performed in the supraperiosteal/submuscular plane) and the temporal area (where the level of injection was above the superficial fascia of the temporal muscle).
Fat will be enriched with PRP in patients of group A.

Study burden and risks

Of each included subject 27 ml of venous blood will be drawn before the start of the operation. Subjects will already be under general anaesthesia for the main procedure during this process. During the regular 1 week post-operative follow-up, the second measurements with the Multi-probe system will be performed. After a period of 3 months and 1 year, additional visits are scheduled for the third and fourth measurements. Duration of each measuring session is estimated at 60 minutes.

PRP is used in several domestic and foreign hospitals for multiple applications at time of this writing.
The measuring equipment used is a non-invasive and painless method of

objectifying skin quality.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Females
* Aged 45-65
* Stable normal BMI (20-25) (1 year stable between 20-25)

Exclusion criteria

* Male

* Aged below 45 or above 65 years
* Aged between 45 and 55 and in the menopause
* Aged between 55 and 65 and pre-menopause
* Prior operations in the mid-face
* Any oncological event in the patients history
* A known psychiatric condition
* A known systemic disease that will impair wound healing (eg diabetus mellitus, known atherosclerosis with an event that required hospitalization, collagen diseases, diseases of the skin).
* Smoking
* BMI <20 or >25 or an unstable BMI: 1 year ± 5 points.
- Pregnancy or active child wish
- Frequent exposure to known carcinogenic substances (eg. work related).
* Active or previous use of hormone replacement therapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2012
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	05-06-2012
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-11-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01461785
CCMO	NL35142.098.11