

[Stem cells shown to restore erection capability in men with erectile dysfunction](#)

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New clinical trial results show that stem cells can restore sufficient erectile function to allow previously impotent men to have spontaneous intercourse. This is the first time stem cell therapy has produced patients who have recovered sufficient erectile function to enable intercourse. This is an early trial, which was primarily addressing safety and dosage (a Phase 1 trial), so the results need to be interpreted accordingly.

In recent years several groups have worked to develop stem cell therapy as a cure for erectile dysfunction, but until now the improvements have not been sufficient to allow affected men to achieve full sexual intercourse. Results presented at the European Association of Urology conference in London show that 8 out of 21 have successfully regained sexual function.

Lead researcher, Dr Martha Haahr (Odense University Hospital) said *“What we have done establishes that this technique can lead to men recovering a spontaneous erection – in other words, without the use of other medicines, injections, or implants. We are now beginning a larger Phase 2 trial to better evaluate its effectiveness and confirm its safety”*.

Erectile dysfunction affects nearly half of men between the ages of 40 and 70 to some degree. There are several possible causes, including surgery (e.g. prostate surgery), high blood pressure, diabetes, cardiovascular disease and psychological problems. Current remedies, which include medications such as PDE5 inhibitors (such as Viagra and Cialis), injections, or penile implants; all have some disadvantages, so scientists have been searching to find a way which restores natural sexual function. The present work focuses on patients with physical damage, caused by surgery (radical prostatectomy) for prostate cancer.

The research group, from Odense in Denmark, used stem cells taken from abdominal fat cells via liposuction (under a general anaesthetic): none of the 21 men reported significant side effects over the trial period, or in the following year. After isolating the stem cells, they were injected into the corpus cavernosum area of the penis. The patients were able to be discharged the same day.

Within 6 months of the treatment, 8 out of the 21 patients reported that they had recovered sufficient erectile function to achieve penetrative) sexual activity. This improvement has been maintained for a year, indicating that this treatment may confer long-term benefits. Only those men who were continent were reported to have recovered sexual function (incontinence is also one of the risks of radical prostatectomy prostate surgery).

Using the generally-accepted IIEF questionnaire to measure erectile function, the whole group of 21 patients reported that their score had increased from 6 before the stem cell transplantation surgery, to 12 after 6 months. However, in the group of men who recovered sexual function, the IIEF score increased from 7 to 14 (the average in men with ‘normal’ sexual function is around 25). This is enough to enable some of the continent men to have a spontaneous erection sufficient for penetrative sex, others achieved this with the help of medication.

Dr Martha Haahr said:

*"We are the first to use a man's own fat stem cells as a treatment for erectile dysfunction in a clinical trial. The technique has been trialed in animal work, but this is the first time stem cell therapy has allowed patients to recover sufficient erectile function to enable intercourse.*

*We are pleased with the preliminary outcomes, especially as these men had previously seen no effect from traditional medical treatment and continue to have good erectile function after 12 months follow-up, indicating that this might be a long-term solution. This suggests the possibility of therapeutic options for patients suffering from erectile dysfunction from other causes. But we need to remember that this is a small trial, with no control group. We're still some time away from a clinically available solution".*

Commenting Professor Jens Sønksen (Herlev, Denmark), member of the EAU Scientific Congress Committee, said

*"This is interesting and novel research looking into the future. The study by Haahr and co-workers is preliminary and more research is needed on the topic. But there is no doubt that stem cell therapy will become an important tool in the treatment of erectile dysfunction. "*

**ENDS**

#### **Notes for Editors**

**PLEASE MENTION THE EUROPEAN ASSOCIATION OF UROLOGY CONGRESS IN ANY STORY RESULTING FROM THIS PRESS RELEASE**

The 32<sup>nd</sup> European Association of Urology conference takes place in London from 24<sup>th</sup> to 28th March. This is the largest and most important urology congress in Europe, with up to 13,000 expected to attend. Conference website <http://eau17.uroweb.org/>

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**How has this work been reviewed?** This work has not gone through a journal peer-review process. This work is amongst the top-rated 150 abstracts (out of 1171 accepted from around 5000 submissions) from the EAU congress. It was reviewed for suitability and accuracy by members of the EAU communications group at more than one stage in development, and subsequently reviewed by a specialist in the field on behalf of the EAU.

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**ABSTRACT: Safety and potential effect of a single intracavernous injection of autologous adipose-derived regenerative cells in patients with erectile dysfunction following radical prostatectomy: 12-month follow-up**  
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## Introduction & Objectives

Cell- and tissue-based therapeutic approaches are progressively gaining ground in the clinics. Evidence from animal models replicating post radical prostatectomy (RP) erectile dysfunction (ED) suggests intracavernous injection of stem cells as a promising treatment approach for ED. The efficacy of current interventions, principally treatment with PDE-5 inhibitors, is not satisfactory and this condition presents an unmet medical need. We report the results of the first human phase 1 trial with autologous adipose derived regenerative stem cells (ADRCs) used freshly isolated after liposuction.

## Material & Methods

21 patients with ED after RP, with no signs of recovery using conventional therapy, were enrolled in this prospective phase 1 open label and single-arm study. All subjects had RP performed at Odense University Hospital, Denmark, 6–17 months prior to enrolment. All men tried full pharmacological intervention (PDE-5 or PGE1 analog) with insufficient effect prior to inclusion. The primary objective was to assess the safety of ADRC in 21 consecutive patients and secondary recovery of erectile function. Each patient received one treatment and was seen 1,3,6 and 12 months after the intracavernosal ADRCs transplantation. Erectile function was assessed by IIEF and EHS scores and any adverse events were reported. Adipose tissue collection was conducted during general anesthesia, and harvesting was performed with water-jet-assisted liposuction. Following immediate isolation of ADRCs, using an automated processing Celution® 800/CRS system, these were injected into corpus cavernosum. ADRC surface markers, viability and ability to differentiate were analyzed. The Danish Health and Medicines Authority and Ethical Committee approval has been obtained. NCT02240823.

## Results

No serious adverse events but 8 minor events (haematoma, sensitive abdominal skin) related to the liposuction were reported. Overall, 8 of 14 (57%) urine continent men recovered their erectile function, and could implement sexual intercourse after 6 months and the effect sustained 12 months after stem cell treatment. Efficacy was solely demonstrated in the patients that were continent at inclusion. Post-hoc stratification according to continent/incontinent status was performed. Accordingly, in continent men IIEF-5 score was unchanged one month after the treatment 6 (4) (median (IQR) (mean 8.5 (95% CI 5.26-11.3)) RM one-way ANOVA with Sidak's multiple comparisons test), but significantly increased after 6 months to 11 (17) (14.27 (9.834 to 18.70),  $p < 0.001$ ) and at 12 months 9 (20) (13.2 (8.833-17.57),  $p < 0.05$ ). In contrast, incontinent men did not regain erectile function (median IIEF6 months= 5 (1) 5.33 (95% CI 4.791-5.875)).

## Conclusions

A single intracavernosal injection of freshly isolated autologous ADRCs statistically significantly improved erectile function in continent men. No serious adverse events were recorded after injection or during follow-up. We suggest that ADRCs represent a safe and promising novel interventional therapy of ED following prostatectomy.