

OSSGROW®

Treatment Guide for new doctor enquiries and first/second time users

Thank you for being a part of **OSSGROW**[®] Bone Cell Therapy. To ensure every patient undergoing the treatment is safe and gets the maximum benefits, we recommend the following steps for achieving a satisfactory clinical outcome.



STEP 1- IDENTIFYING THE RIGHT PATIENT



STEP 2- TREATING THE PATIENT



STEP 3- FOLLOW-UP OF THE PATIENT

OSSGROW[®] is covered under cashless reimbursement schemes from all major Private/Central Government and State Health Insurance Schemes.

OSSGROW[®] Bone Cell Therapy has proven its safety and efficacy in clinical trials and Post Marketing Surveillance studies in India. According to the clinical data analysis, most of the patients with AVN of femoral head qualify for treatment with **OSSGROW**[®], however, every AVN patient may not be eligible. Therefore, it is essential to identify suitable patients for the treatment.

STEP 1- IDENTIFYING THE RIGHT PATIENT

01



1A. ASSESSMENT OF CLINICAL HISTORY AND CURRENT MEDICAL CONDITIONS

Avascular Necrosis (AVN) is a debilitating bone condition triggered by several factors, such as alcohol consumption and excessive steroid intake. Hence, checking the patient's medical history is crucial for better clinical understanding and prognosis. Do take note of the patient's concomitant medication and co-morbidities, if any. Do ensure the patient is currently NOT associated with any of the following:

- Cancer being either haematological malignancy or solid tumors
- Multiple Sclerosis, SMA, and AIDS, Active bone infection
- Unable to reduce their high-dose steroid consumption as a part of an ongoing treatment regimen
- On-going chemotherapy/radiation treatment
- Undergone participation in any Clinical Trials in the last 1 year

- Received PRP, BMAC, CAR-T or Gene Therapy in the last 6 months
- Previously undergone organ or bone marrow transplant in the last 6 months
- Pregnancy, breast-feeding or having a positive pregnancy test before receiving the therapy
- Patients on wheelchairs (autophagic or paraplegic)
- Patients aged 18 years and above only

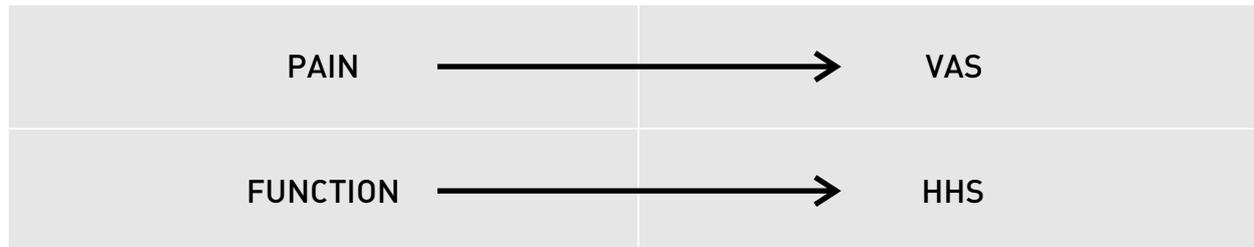
If the patient has frequent consumption of alcohol or smoking, ensure he/she is willing to reduce or quit the same.



1B. STAGING OF AVN

- Confirm the Stage of AVN: X-ray and Magnetic Resonance Imaging (MRI) can be used to determine the Stage of AVN
 - **X-ray**: Observe lesion or crescent sign in Standing AP and Lateral view to confirm AVN
 - **MRI**: Evaluate the radiographic features to determine the AVN Stage
 - **OSSGROW[®]** is not applicable for the advanced stages (Stage 3B - 4)
- Suggested capture of patient's pain and functional scores to understand their baseline levels

PREOPERATIVE



[VAS- Visual Analogue Score](#)

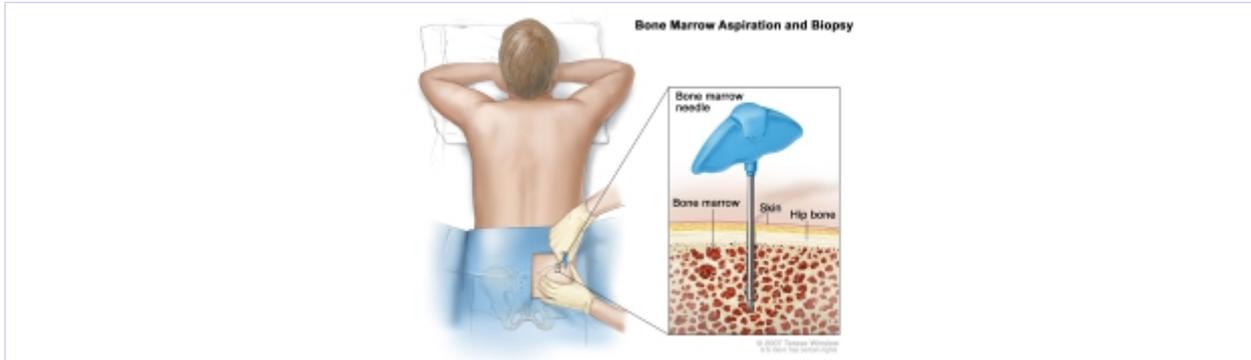
VAS score should decrease with treatment

[HHS- Harris Hip Score](#)

HHS score should increase with treatment

STEP 2- TREATING THE PATIENT

04



2A. BONE MARROW HARVEST (BMH)

BMH is the first step of the treatment procedure. An **OSSGROW®** BMH Transport Kit will be sent to the hospital in cold chain on or before the assigned date of the procedure.

Regrow's trained paramedical staff will carry this kit to ensure maximum compliance and ease of logistics. Refer to BMH Manual here for detailed treatment procedure

- Refer to the BMH manual for step by step guidance
-  our team for more information as required

For clinical references of BMH, you may refer to some publicly available literature here:

- [Bone Marrow Biopsy Procedure Instructions And Information](#)
- [Medical Procedure Bone Marrow Aspiration And Biopsy A.I. Onaga](#)

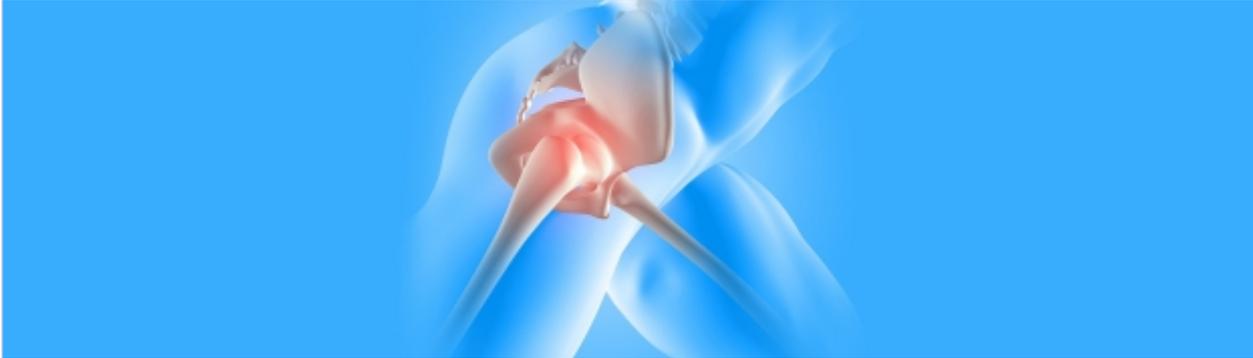




2B. REGROW CELL CULTURE

Once the BMH procedure is complete, the BMH Transport kit is collected by our team and transported to Regrow's Cell Processing Centre located in Lonavala, Maharashtra. The cells are cultured in Regrow's GMP facility for approximately 4 weeks.

- Regrow Operations Team will update you regarding the quantity/quality of the cell yield within the first 10 days upon receipt of the Transport Kit
- In case the initial cell yield is unfavorable, we may advise you to repeat the BMH procedure. However, the chances of this are below 5%
- Once the cells are successfully cultured beyond a certain phase, the team will coordinate with you and the patient to fix the suitable cell implantation date and time



2C. FINAL PRODUCT IMPLANTATION

Implantation is the last step of the treatment procedure. A fresh patient X-ray is recommended before cell implant to capture the exact location of the necrotic lesion/area.

The **OSSGROW**[®] Delivery Kit will be sent to the hospital in cold chain on the assigned date of the procedure along with Regrow's trained paramedic staff. Before performing the implant, please Refer to the Implantation manual for a step by step guidance, or:

Educate the patient about the post-treatment care and rehabilitation program. Since each patient's program would be customized basis their medical condition and needs, **Regrow**[®] has prepared an **OSSGROW**[®] Treatment-related Rehabilitation Manual for Patients with unilateral or bilateral disease.

It is available to be viewed here:

- [Rehabilitation Manual for Unilateral and Bilateral Disease](#)



STEP 3- FOLLOW-UP OF THE PATIENT

09



Follow-up of the patients is crucial to determine their safety, disease progression, and benefit of the overall treatment provided.

Suggested PROM (Patient Related Outcome Measure Score) and Radiology Assessment is mentioned below with their respective timelines:

3 Months after implant	VAS + X-Ray	1 Year after implant	X-Ray + VAS + HHS
6 Months after implant	X-Ray + VAS + HHS	2 Years after implant	X-Ray+ MRI + VAS + HHS

We would like to take this opportunity to inform you that Regrow has prepared a “Patient Pack” that include:

- Product Flyer, Surgery Prep Guide, and Rehabilitation Manual
- If you would like to receive the Patient Packs, do let us know, and we will gladly provide them at your clinic or hospital premises
- For more information, visit: www.ossgrow.com

OSSGROW® BONE CELL THERAPY PUBLICATIONS

1. [Retrospective Study on Implantation of Autologous Cultured Osteoblasts for the Treatment of Patients with Avascular Necrosis of the Femoral Head](#)
2. [Hip Preservation With Autologous Osteoblast Cell-Based Treatment in Osteonecrosis of the Femoral Head](#)
3. [A Prospective Monocentric Report On The Use Of Autologous Adult Live Cultured Osteoblast \[OSSGROW®\] For The Treatment Of Patients With AVASCULAR NECROSIS OF THE HIP](#)

Please Reach Out To Us:



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THANK YOU!