



Since 1930

**AVN Ayurveda**



# **ZEOTONE<sup>®</sup> PLUS CLINICAL TRIALS**

---

**Complete Study Data**

# OVERVIEW



A double-blind, prospective, multicentric, randomized, three-arm, clinical study to evaluate the efficacy, safety and tolerability of polyherbal formulation Zeotone® Plus in comparison with placebo and a formulation containing glucosamine and chondroitin sulphate in the treatment of osteoarthritis in adult subjects, was conducted.



Composition:  
Each soft gelatin capsule contains 1000 mg of medicament prepared out of

Gandha talam		150,000 mg
Tila Taila	Sesamum indicum (Seed Oil)	150,000 mg
Goduggha		0.870 m
Aqueous extract of		
Sh-Guggulu	Commiphora wightii (Exud.)	400,000 mg
Sankha Bhasmam		40,000 mg
Kunduru	Buxuswella serrata (Exud.)	40,000 mg
Hindra	Curcuma longa (Rz.)	20,000 mg
Ashwambhari	Cissus quadrangularis (St.)	0.070 mg
Manabala	Sida rhomboides (Rz.)	0.070 mg
Bilwa	Angele marmelos (Frt.Pulp.)	0.010 mg
Syonaka	Chrysanthemum indicum (Rz.)	0.010 mg
Agurmantha	Chondrodendron pholidos(Rz.)	0.010 mg
Gandharvi	Cimicifuga racemosa (Rz.)	0.010 mg
Palata	Sternocarpum suaveolens (Rz.)	0.010 mg
Tava	Hardium vulgare (Rz.)	0.010 mg
Kola	Zizyphus jujuba (Frt.Pulp.)	0.010 mg
Kulathra	Vigna unguiculata (St.)	0.010 mg
Plate of		
Drosera	Cedrus deodara (H.Wit.)	0.001 mg
Tagara	Valeriana wallichii (Rz.)	0.001 mg
Yasasradhu	Glycyrrhiza glabra (Ste. & R.)	0.001 mg
Bolan	Commiphora myrrha (Exud.)	0.001 mg
Mashpami	Tenaculum labiale (Rz.)	0.001 mg
Mudgapani	Vigna trilobata (W.P.)	0.001 mg
Malli	Zingiber officinale (Rz.)	0.001 mg
Saltavari	Agaveguz racemosa (Rz.)	0.001 mg
Kohlasakari	Fibrella zeyheri (Rz.)	0.001 mg
Asavagandha	Mitharia comifera (Rz.)	0.001 mg
Saunha	Aquarium sowa (Fr.)	0.001 mg
Sandhava lavana	Rock salt	0.001 mg

A PROPRIETARY AYURVEDIC MEDICINE

# OVERVIEW



## Why was the study conducted?

Being an innovator & expert in Ayurveda, after years of clinical experience & research we created an Ayurvedic medicine & wanted to validate it using modern clinical trials to ensure the scientific community understands the efficacy and safety of our product Zeotone® Plus to make sure many more people benefit out of our medicine.



## Who conducted the study?

CRO - Auros Health care R&D India Private Limited (AHC/179/RDD/CR/EE/17). The study was registered under the CTRI - (Registration number is (CTRI/2017/12/010838)



## Where was the study conducted?

Centres of the study were;

- SMC Ortho & Trauma Clinic (No: 12/1, Violet Flats, Mogappair West, Chennai)
- S.V Multi Speciality Hospital #177(77), Rangarajapuram Main Road, Kodambakkam, Chennai)



## Trial Subjects Enrolment

Enrolment of subjects was with strictly defined inclusion and exclusion criteria. Randomization & blinding was done into two treatment arms and a placebo arm in a 1:1:1 ratio.



# SUBJECT GROUPS

Three groups were formed



## Treatment arm 1

Polyherbal formulation  
Zeotone® Plus:  
29 subjects



## Treatment arm 2

Glucosamine and  
chondroitin sulphate:  
23 subjects



## Placebo arm 3

Placebo:  
20 subjects

### Inclusion Criteria

- Adults between 30 and 65 years of age with confirmed diagnosis or known history of osteoarthritis, with a moderately active lifestyle. (both sexes and ages inclusive)
- Subject with Grade II or III of Kellergen Lawrence (KL) Grade.
- Subject with pain (Pain Scale score  $\geq 4$ ) on walking in one or both knees 24 hours prior to screening.
- Subjects with BMI  $\leq 30$  at the time of screening.
- Subjects who are ambulatory, requiring but not currently receiving or not satisfied with anti-inflammatory or anti-analgesic drugs





# SUBJECT GROUPS

## Exclusion Criteria

- Subjects with known hypersensitivity to herbal investigational products or their constituents.
- Subjects with known hypersensitivity to NSAID, aspirin, COX-2 inhibitors and other analgesic medicine.
- Subjects who have had hyaluronic acid injections, up to 6 months prior to enrolment.
- Subjects who have had an Intra-Articular Steroid, up to 3 months prior to enrolment.
- Subjects with immuno compromised state
- complications.
- Significant (requiring surgical correction) Valgus or Varus deformity of the knee, ligamentous laxity, or meniscal instability.
- Concomitant inflammatory or any other disease/condition which may affect joints (e.g., rheumatoid arthritis, metabolic bone disease, psoriasis, gout, pseudogout, chondrocalcinosis etc.)
- History of sepsis in any joint or any clinical concern for a sub-acute infectious process in the target joint.
- History of surgery in the target joint.
- Planned surgery on any lower extremity joint.
- Clinically significant venous or lymphatic stasis is present in the leg(s).
- Clinically apparent tense effusion or inflammation at the target knee.
- Any musculoskeletal condition that would impede measurement of efficacy at the target joint
- Subjects with uncontrolled diabetes, hypertension, or congestive heart failure.

## The following scales were used for baseline and outcome measures of efficacy.



WOMAC (Western Ontario & McMaster universities arthritis index)



VAS (Visual analogue scale) for the measurement of pain



QoL (Quality of life questionnaire)



Physicians Global Impression of Change

# RESULTS-1

## Reduction in WOMAC



Zeotone® Plus: 100% of Subjects have achieved a reduction of at least 20 in the WOMAC score from Visit 1 to Visit 4. ( $Z = 5.29$ ,  $p = 0.000 < 0.05$ ).

**There was a mean reduction of 36% between the scores from Visit 1-4**



Glucosamine + Chondroitin Sulphate: Only 54.5% Subjects have achieved a reduction of at least 20 in WOMAC score from Visit 1 to Visit 4. ( $Z = 0.43$ ,  $p = 0.335 > 0.05$ ).

**There was only a mean reduction of 24% between Visits 1-4**

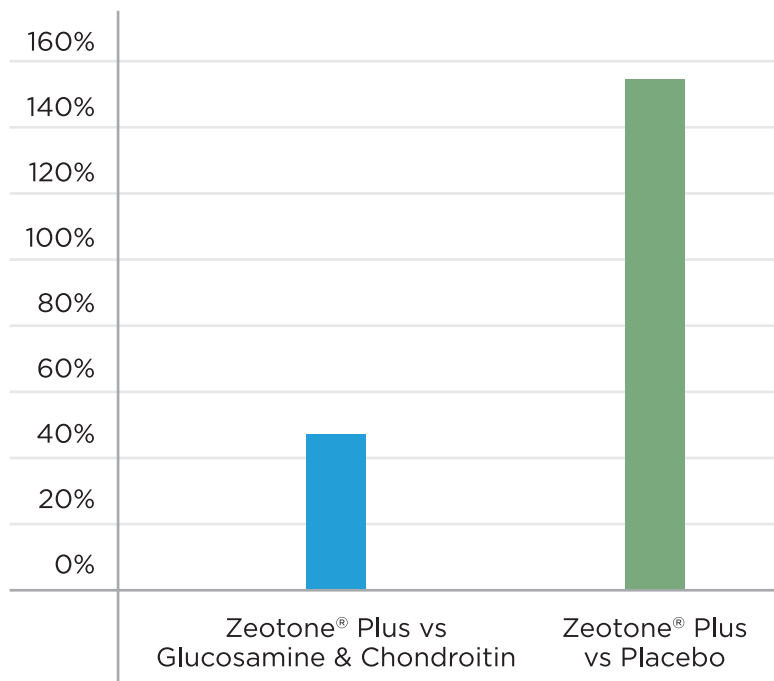
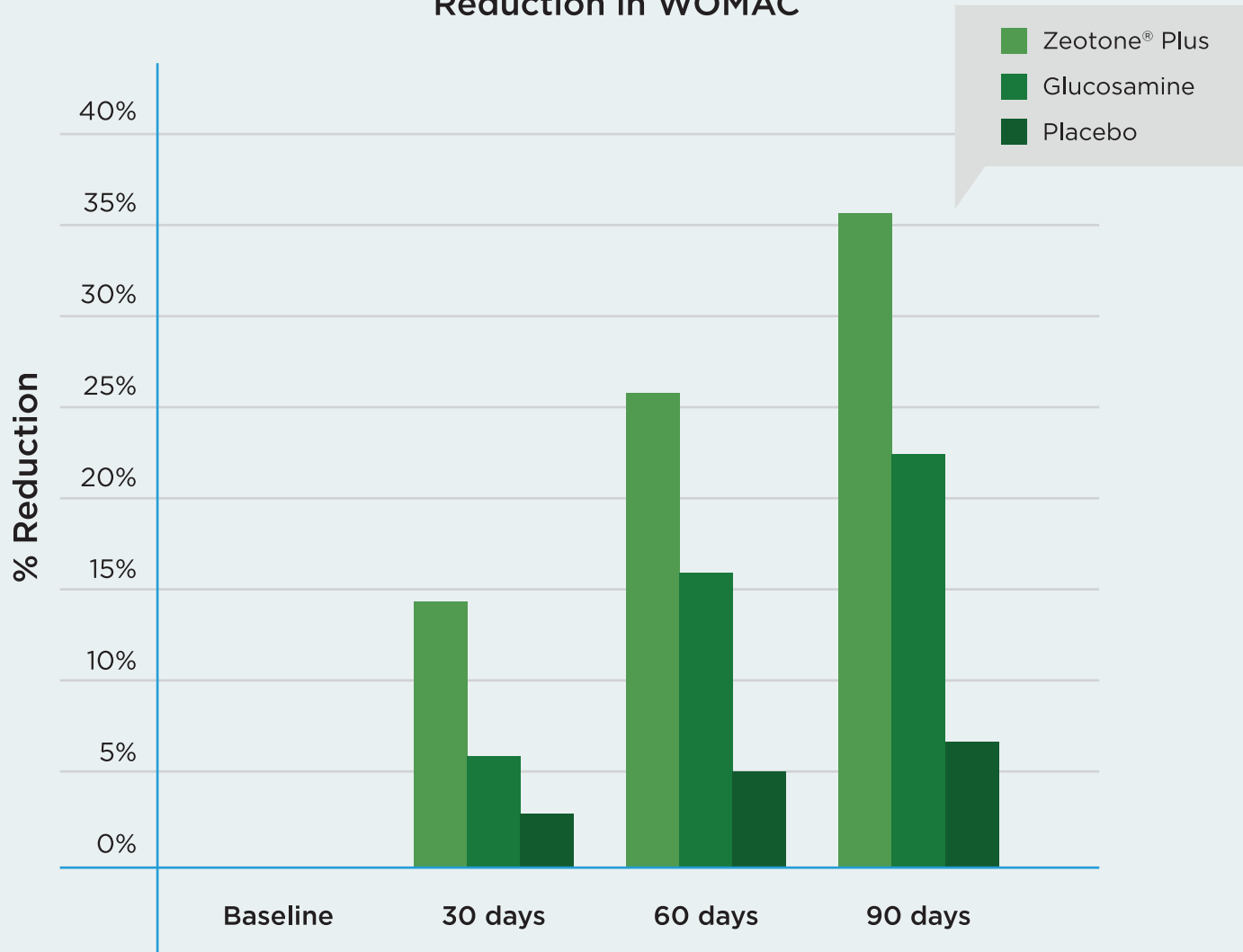


Placebo 0% Subjects have achieved a reduction of at least 20 in WOMAC score from Visit 1 to Visit 4. ( $Z = -4.36$ ,  $p = 1.000 > 0.05$ ).

**There was only a 6% reduction in WOMAC scores in the placebo group**

# RESULTS-1

Reduction in WOMAC



143%

40%

- Zeotone® Plus Was 40% more effective than glucosamine and chondroitin in the management of osteoarthritis as evidenced by the WOMAC scale
- Zeotone® Plus was 143% more effective than placebo in the management of Osteoarthritis



# RESULTS-2

## Reduction in VAS



Zeotone® Plus: 93% of Subjects have achieved a reduction of at least 4 on the Pain Scale from Visit 1 to Visit 4. ( $Z = 4.54, p = 0.000 < 0.05$ ).

**There was a 70% reduction in pain for patients in the study group between Visits 1 and 4.**



Glucosamine + Chondroitin Sulphate: Only 23% of subjects have achieved a reduction of at least 4 in Pain Scale from Visit 1 to Visit 4. ( $Z = -2.56, p = 0.995 > 0.05$ ).

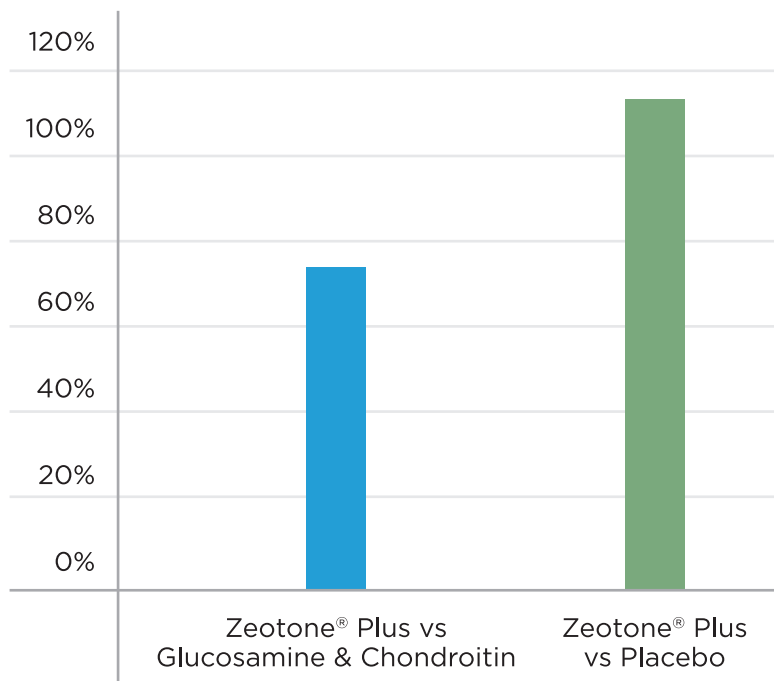
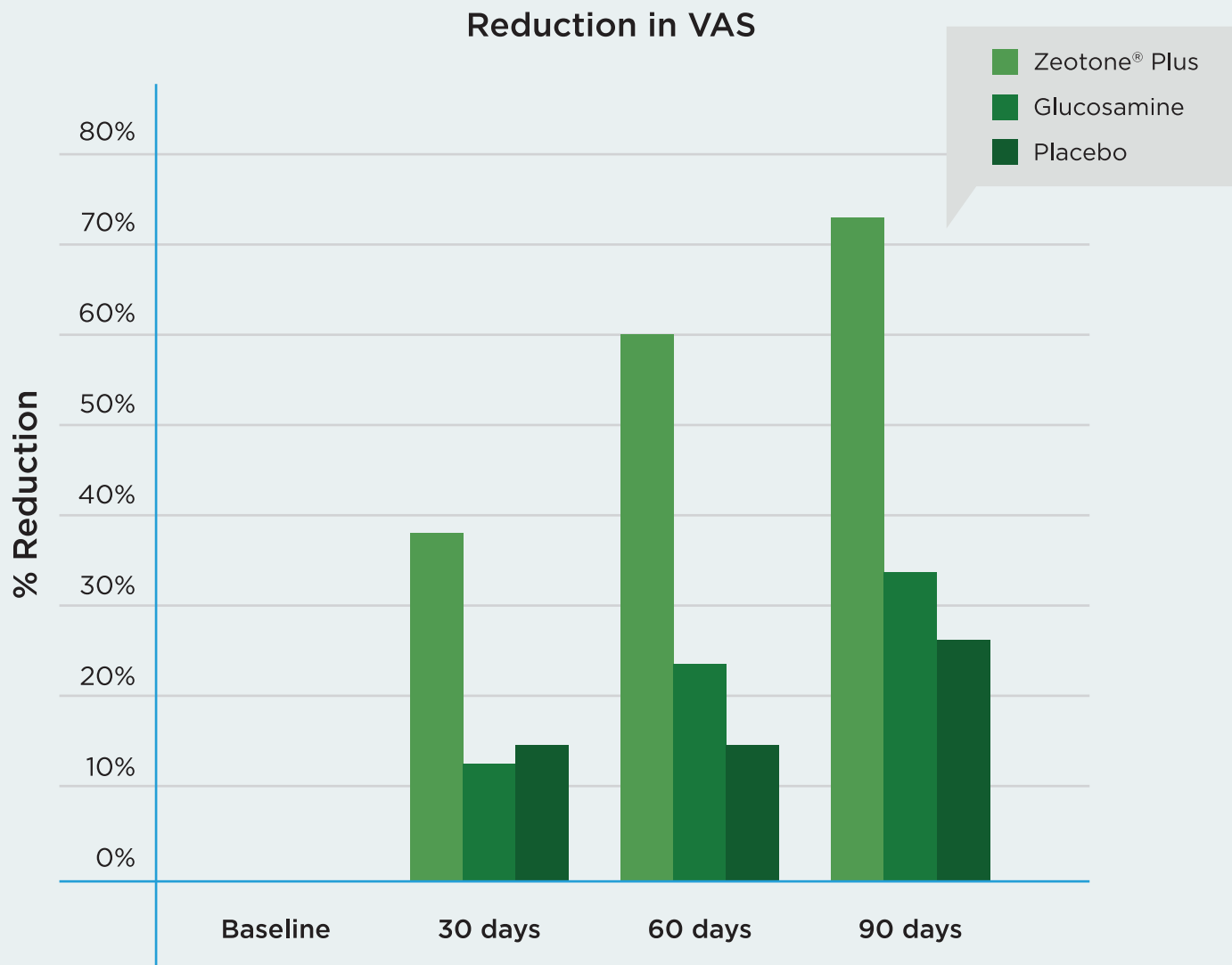
**There was only 33% reduction in pain between Visits 1 and 4 in the control group.**



Placebo: 0% Subjects have achieved a reduction of at least 4 in the Pain Scale from Visit 1 to Visit 4. ( $Z = -4.36, p = 1.00 > 0.05$ ).

**There was only 22% reduction in pain between Visits 1 and 4 in the placebo group.**

# RESULTS-2



104%

72%

- Zeotone® Plus was 72% more effective than Glucosamine and chondroitin in reducing pain due to Osteoarthritis.
- Zeotone® Plus was 104% more effective than Placebo in reducing pain due to Osteoarthritis.

# RESULTS-3

## Improvement in QoL



Zeotone® Plus: 100% of Subjects have achieved an improvement of at least 10 in QoL score from Visit 1 to Visit 4. ( $Z = 5.29$ ,  $p = 0.000 < 0.05$ ).

**There was a mean increase of 69% in the Quality of Life of people in the Study group**



Glucosamine + Chondroitin Sulphate: Only 45% of Subjects have achieved an improvement of at least 10 in QoL score from Visit 1 to Visit 4. ( $Z = -0.43$ ,  $p = 0.665 > 0.05$ ).

**There was a mean increase of 47% in the Quality of Life of people in the Control group**



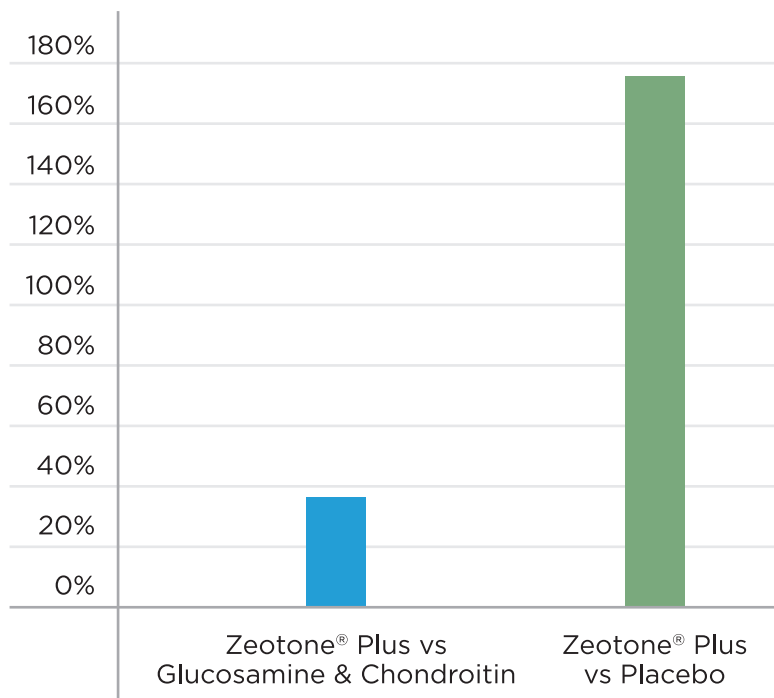
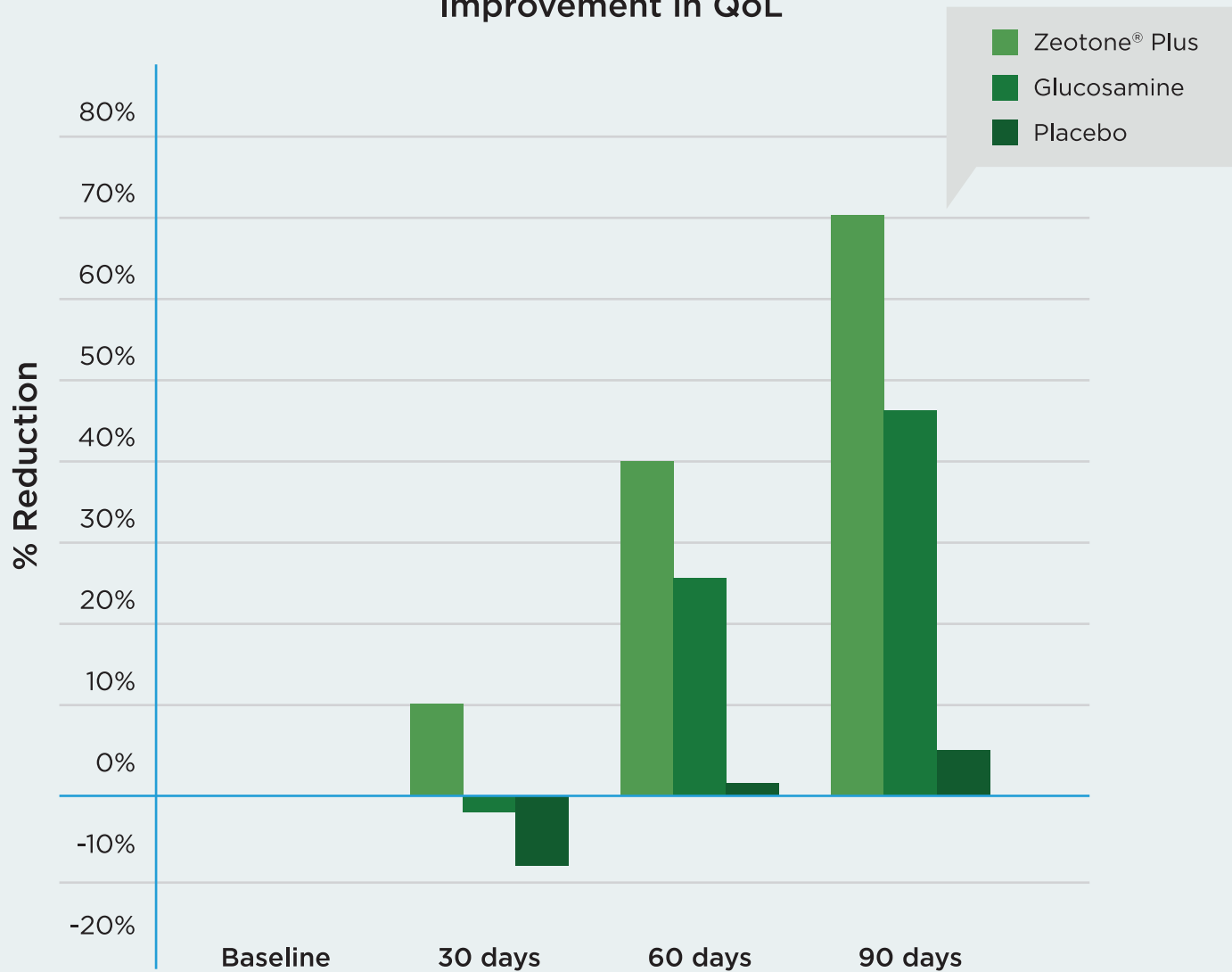
Placebo: 0% Subjects have achieved an improvement of at least 10 in QoL score from Visit 1 to Visit 4. ( $Z = -4.36$ ,  $p = 1.00 > 0.05$ ).

**There was only a 5% increase in the Quality of Life of people in the Placebo group**



# RESULTS-3

## Improvement in QoL



172%

38%

- Zeotone® Plus was 38% more effective than Glucosamine and chondroitin in improving the quality of life of patients.
- Zeotone® Plus was 172% more effective than Placebo in improving the quality of life of patients.

# RESULTS-4



Zeotone® Plus: 100% subjects have achieved a score of 2 or 1 in “Physician’s Impression of Change Scale” by end of treatment.  
(Z = 5.29, p = 0.000 < 0.05)



Glucosamine + Chondroitin Sulphate: Only 23% subjects have achieved a score of 2 or 1 in “Physician’s Impression of Change Scale” by end of treatment.  
(Z = -2.56, p = 0.995 > 0.05)



Placebo: 0% subjects have achieved a score of 2 or 1 in “Physician’s Impression of Change Scale” by end of treatment  
(Z = -4.36, p = 1.00 > 0.05)

## Recurrence Of Pain After Treatment



up to 4 weeks

### Zeotone® Plus

The recurrence of pain and/or symptoms of osteoarthritis did not occur up to 4 weeks, after stopping treatment. According to the data analysed it is confirmed that 100% of the subjects achieved a Secondary End Point of 11-20% variation between end of treatment and the recurrence of pain/symptoms.

(Z = 5.29, p = 0.000 < 0.05).



up to 3 weeks

### Glucosamine & Chondroitin Sulphate:

The recurrence of pain and/or symptoms of osteoarthritis did not occur up to 3 weeks, after stopping treatment. According to the data analysed it is confirmed that 91% of the subjects showed >20% variation between the end of treatment and the recurrence of pain/symptoms.

(Z = -3.71, p = 1.000 > 0.05).



within 1 week

### Placebo

The recurrence of pain and/or symptoms of osteoarthritis did not occur within 1 week, after stopping treatment. According to the data analysed, it is confirmed that 100% of the subjects showed >20% variation between the end of treatment and the recurrence of pain/symptoms.

(Z = -3.90, p = 1.000 > 0.05).

# RESULTS-5

## Other observations



No adverse events related to the drug reported



No statistically significant difference in LFT & RFT between Visits 1 & 4 in the study group



No statistically significant difference in CBC between Visits 1 & 4 in the study group





# RESULTS: SUMMARY



Zeotone® Plus was 40% more effective than Glucosamine and Chondroitin in the management of osteoarthritis as evidenced by the WOMAC scale



Zeotone® Plus was 72% more effective than Glucosamine and Chondroitin in reducing pain due to Osteo-arthritis.



Zeotone® Plus was 38% more effective than Glucosamine and Chondroitin in improving the quality of life of patients.



Zeotone® Plus was more effective; with a final score of 1 or 2, indicating "Very Much Improved" from baseline as per Physician's Global Impression of Change, upon treatment for 3 months.

# RESULTS: SUMMARY



Upon the end of treatment, the recurrence of pain/symptoms was seen;

- Only after 4 weeks for Zeotone® Plus
- After 3 weeks for Glucosamine & Chondroitin Sulphate
- Within 1 week for Placebo.



Zeotone® Plus was more effective than Glucosamine & Chondroitin Sulphate in sustaining the effect even post-treatment showing <20% variation between end of treatment and recurrence of pain/symptoms.



There were no adverse events reported and no difference in any safety parameters



It was concluded that Zeotone® Plus is better than the combination of Glucosamine and Chondroitin in the management of Osteoarthritis.



**AVN Ayurveda**

*For further information write to:*

**AVN Ayurveda Formulations Pvt. Ltd.**

175 Vilachery main road, Muniyandipuram, Madurai - 625004  
customer care@avnayurveda.in | [www.avnayurveda.com](http://www.avnayurveda.com)

*Authentic Ayurveda...Modern Approach*