



Safety & Efficacy of a Single Injection of Mannitol-modified Cross-Linked Hyaluronic Acid (HAPPYMINI®) in patients with Temporo-Mandibular Osteoarthritis

ARTEMIS Study

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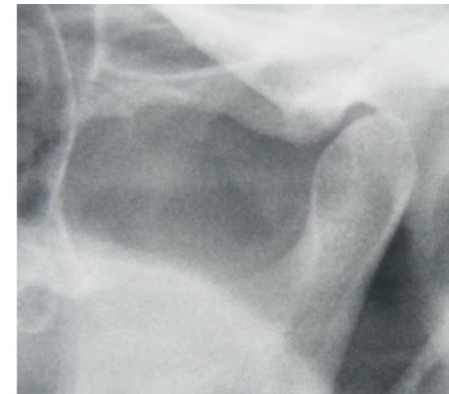
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Temporo-Mandibular joint (TMJ) Osteoarthritis

- **Common causes of face arthromyalgias (dental apparatus disorders)**
- **A wide range of symptoms :**
 - TMJ pain;
 - Functional disorders such as limitation of mouth opening, assessed by the inter-incisal distance, sometimes related to the disk luxation (or meniscus), blocking, joint sounds and other signs such as bruxism, earaches or tinnitus ...



Temporo-Mandibular joint (TMJ) Osteoarthritis

➤ Treatment:

- Empirical measures, routinely prescribed without real evaluation (pain killers, NSAIDs, muscle relaxants).
- Use of bite guards and/or occlusal equilibrations by the addition of composite resin.
- In case of failure of the first line treatments :
 - Corticosteroids infiltrations => transitory efficacy
 - Hyaluronic acid (HA) injection



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- **Methods :** 6-month prospective pilot study (N° EUDRACT 2016-A00177-44).
- **Objective :**
 - To assess the safety and efficacy of a single injection of HAPPYMINI® 1ml, in the treatment of TMJ OA.
- **Patients et methods :**
 - Patients suffering from symptomatic TMJ OA, unrelieved by pain killers and/or NSAIDs and/or use of bite guards.
 - Intervention : every patients received an injection of 1ml of **HAPPYMINI®**, 1,6% concentrated cross-linked HA combined with 3,5% of mannitol, in the painful TMJ.
- **Response to the treatment assessed by :**
 - Decrease of pain at palpation and at mastication on a 10 point numeric scale;
 - Improvement of the inter-incisal distance : mouth opened at the widest;
 - Improvement of functional disorders: bruxism, joint sounds, drug therapies;
 - Patients self assessment of satisfaction



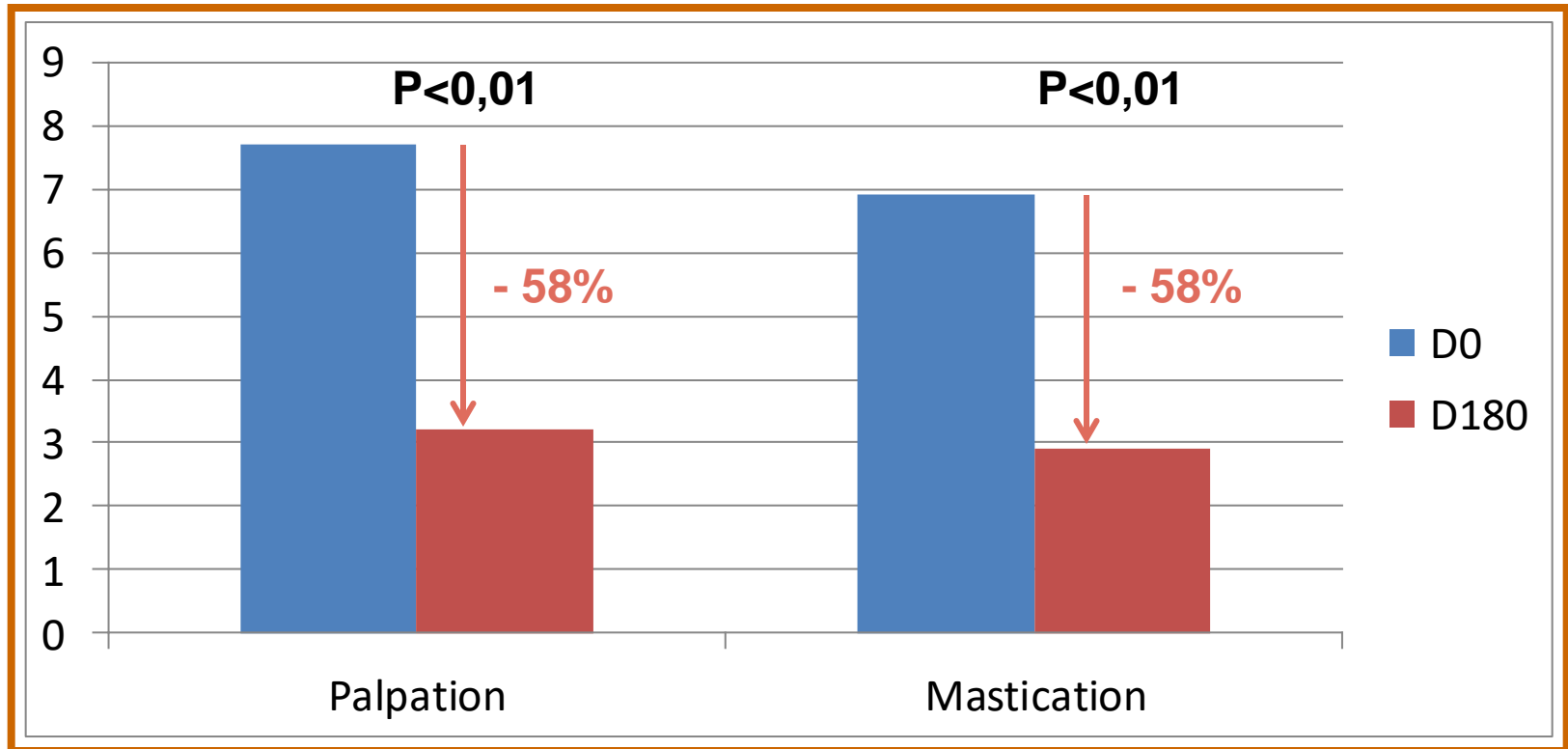
ARTEMIS STUDY

POPULATION AT D0

Number of patients included	36
Number of temporo-mandibular OA	48 : 19 unilateral and 17 bilateral
Age % [range]	14%]40-50] – 42%]50-60] – 25%]60-70]
Sex F/M %	75/25
Average BMI	24.5 kg/m ²
Mean disease duration	98 months
Treatment	NSAIDs : 44% - Pain killers: 83%
Mean Pain at Mastication D0 (0-10)	6.9
Mean Pain at Palpation D0 (0-10)	7.7
Mean inter incisal distance	29 mm

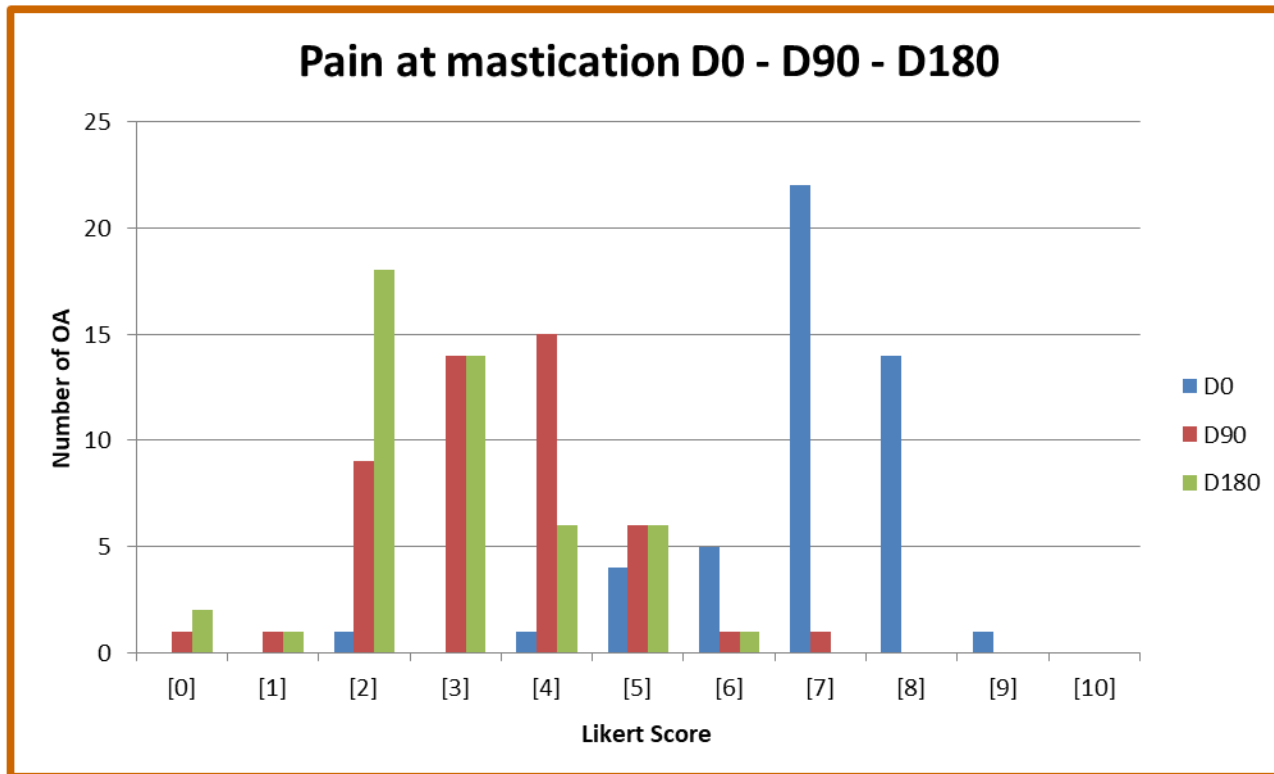
Results

Pain variation between Day 0 et Day 180



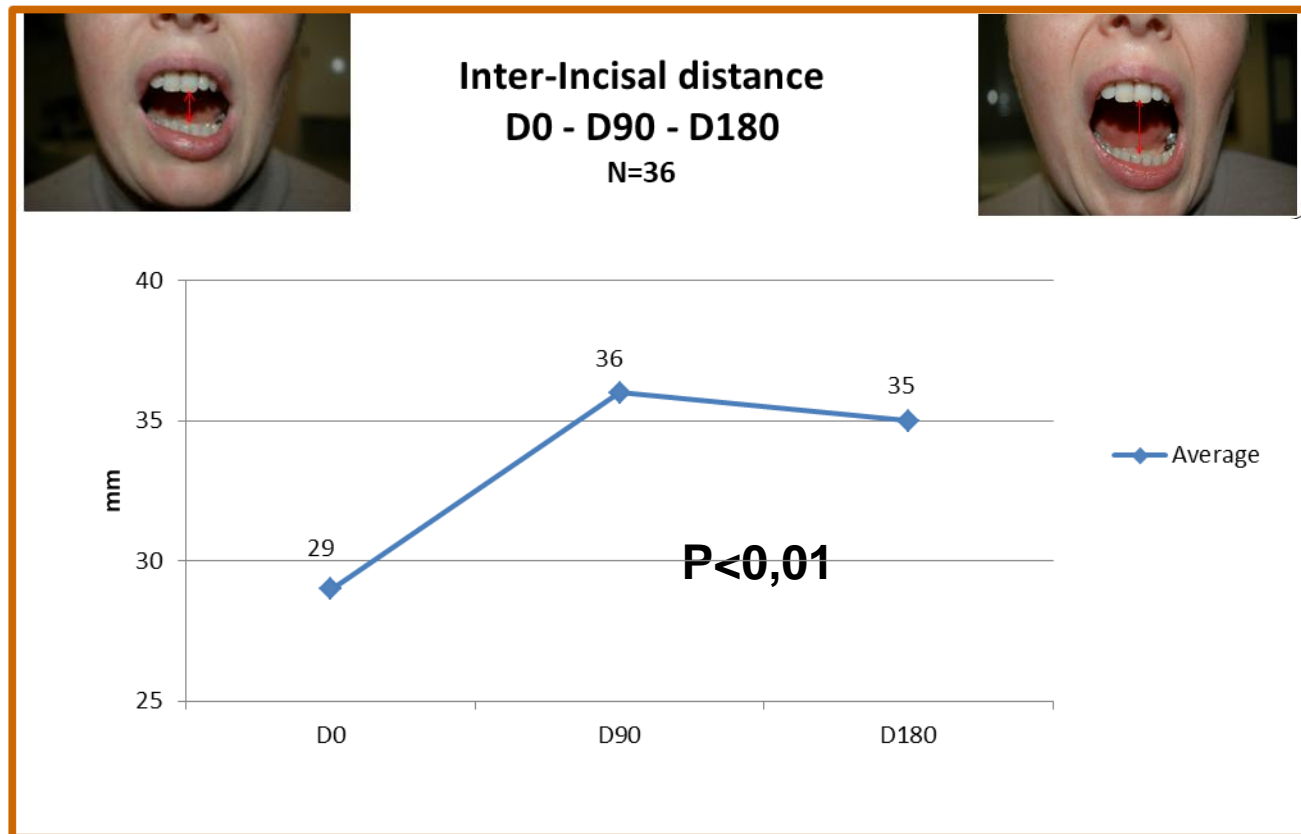
Results

Pain variation between D0 et D180 Individual data



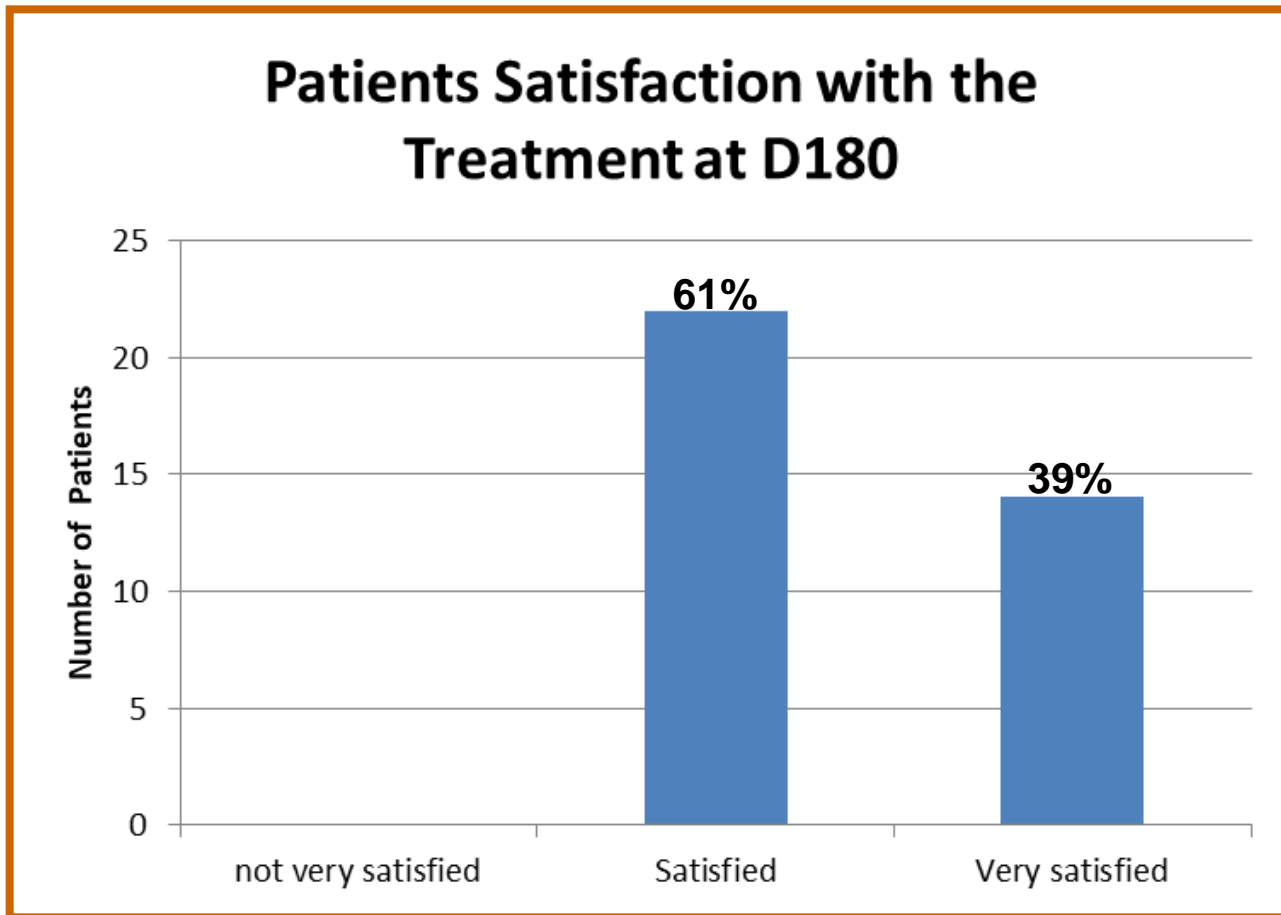
Results

Improvement of the inter-incisal distance between D0 et D180



Results

100% of patients satisfied at D180



Conclusion

Despite the absence of a control group, **this pilot study strongly suggests that a single injection of HAPPYMINI[®] is an effective and safe treatment for TMJ osteoarthritis**, with long lasting pain and manducatory function improvment, **even in patients with long-lasting disease.**

