

# Effectiveness, safety, and routine use of TEOSYAL® PureSense Redensity 2 treatment in the periorbital region

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# The appearance of the periorbital region is a frequent concern of patients seeking rejuvenation treatment



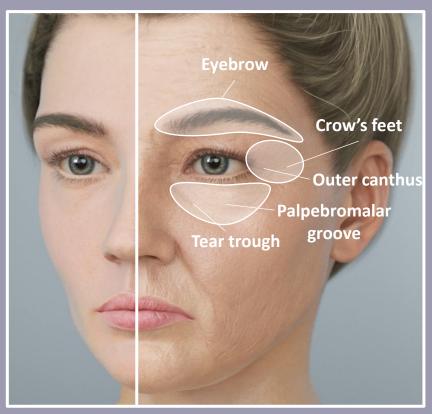
The periorbital area is essential in facial aesthetic perception<sup>1</sup> as it:

- plays a key role in conveying emotions through facial expressions<sup>2</sup>
- is the hallmark of the aging status and fatigue of the entire face<sup>1,3</sup>



- 78.8% of patients seeking minimally invasive procedures expressed interest in improving the appearance of their periorbital region<sup>4</sup>
- Hyaluronic acid (HA) dermal fillers have gained popularity as an effective, non-surgical alternative to improve the appearance of the periorbital region<sup>5,6</sup>

#### **Periorbital indications**



#### **TEOSYAL® PureSense Redensity 2**



## 10-years

#### of use in clinical practice

for the correction of fine lines/wrinkles affecting a withered skin marked by signs of ageing, and the treatment of the under eyes circles, including the tear trough<sup>7-9</sup>

### Clinically proven efficacy and safety in the tear trough<sup>8,9</sup>

of patients and physicians perceived an aesthetic improvement

of patients reported no side effects

of patients described marked or moderate satisfaction

Hyaluronic Acid (HA) concentration	15 mg/mL
Formula composition	Mix of crosslinked & noncrosslinked HA
Degree of Modification (MoD) BDDE crosslinking	5.5%
Lidocaine	0.3%
Supplemented* phosphate buffer pH 7.3	q.s. ad 1 mL
Packaging	2 x 1 mL
Needle	30G x 1/2"

#### High malleability and spreadability<sup>2,8-10</sup>

Low strength, low rigidity, and low resistance to compression

#### Low hygroscopy<sup>2,8-10</sup>

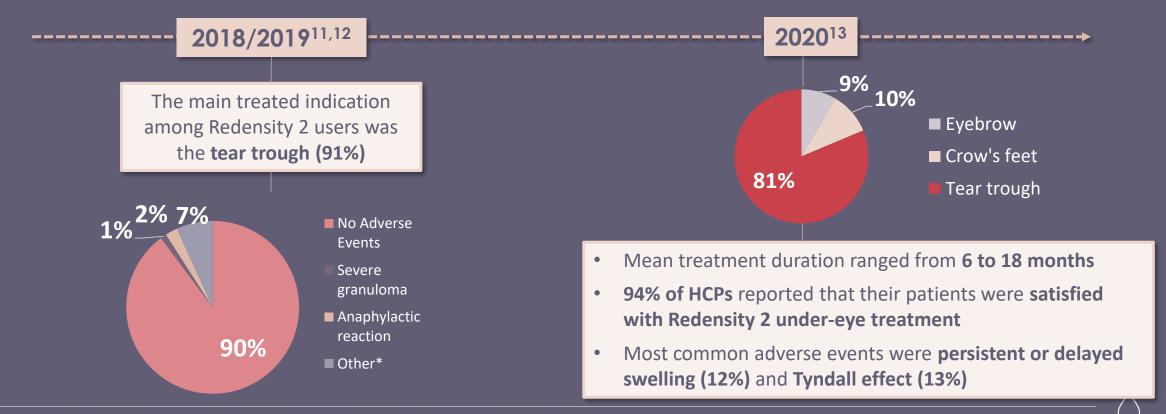
Combination of crosslinked and non-cross-linked HA, at a low HA concentration, allows for minimal water absorption → minimal swelling

**Redensity 2** formulation and rheological properties make it the elective gel to evenly fill the under-eye circles, in particular the tear trough



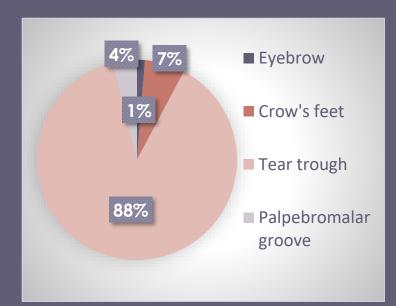
#### Global Post-Market Surveillance (PMS) Surveys – Redensity 2<sup>11-14</sup>

- Proactive **real-world evidence (RWE)** collection to support Post-Market Surveillance activities, such as the Post-Market Clinical Follow-up (PMCF) report
- PMS surveys gather **insights from worldwide practitioners** and highlight global uses and trends related to TEOSYAL® products
- Powerful tool to reinforce Teoxane's awareness on the **routine use, performance and safety** of TEOSYAL® products

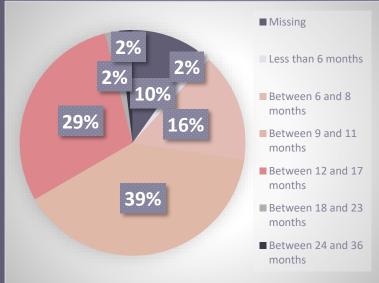


------ 2021<sup>14</sup> -----

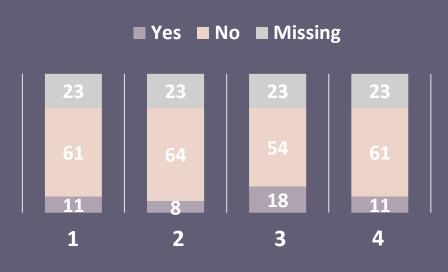
Within the periorbital region, the **tear trough** represented most of the treatments with Redensity 2



Most practitioners reported a performance duration of 6 to 18 months in the tear trough



**Good safety profile** with low incidence of adverse events and no reported serious adverse events



- 1: Pain at the injection site/ Tenderness
- 2: Redness/ Erythema
- 3: Bruising/ Haematoma/ Ecchymosi/ Injection site bleeding
- 4: Immediate-transcient swelling/ Oedema



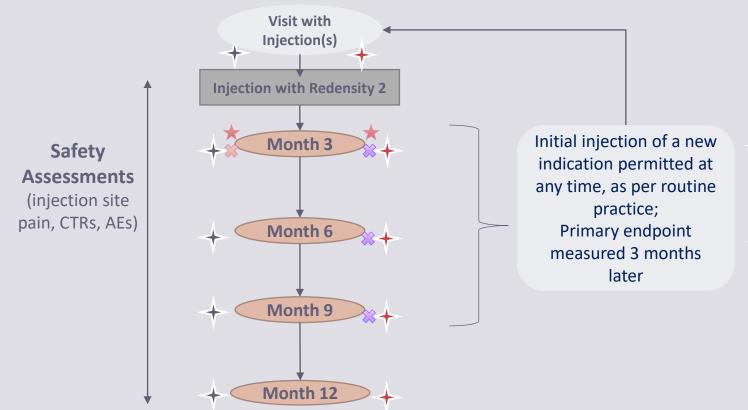




A prospective, observational registry conducted in Europe with a similar study design to the GRADUAL registry 15,16

Objective: gather RWE to assess the effectiveness, safety and routine use of TEOSYAL® PureSense Redensity 2 for aesthetic treatments, including treatments performed in the periorbital area

#### **EYELIGHT study design**



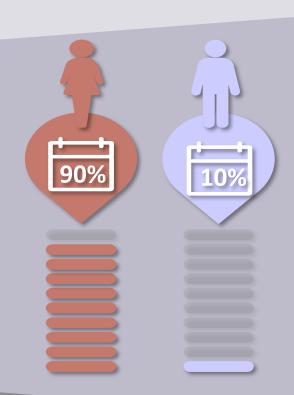
- Primary endpoint proportion of subjects deemed "improved" or "much improved" on the GAIS at Month 3, as assessed by both the Investigator and the Subject
- Proportion of subjects deemed "improved" or "much improved" on the GAIS as assessed by the Investigator
- Proportion of subjects deemed "improved" or "much improved" on the GAIS as assessed by the Subject
- Subject Satisfaction
- Investigator Satisfaction with the device and ease of injection



## Demographic characteristics of the general population









Mean age: 48 years old [23;77] 39% treated with Redensity 2



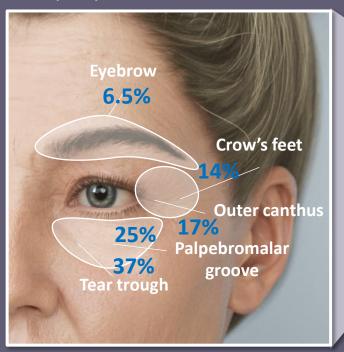


Fitzpatrick 41% Type II 33% Type III 16% Type IV

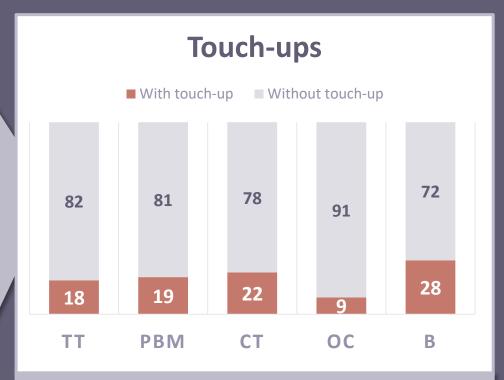
# Almost all injectors were satisfied with initial Redensity 2 treatment, and only 19% of the subjects required touch-ups



Number of initial injections per periorbital indication



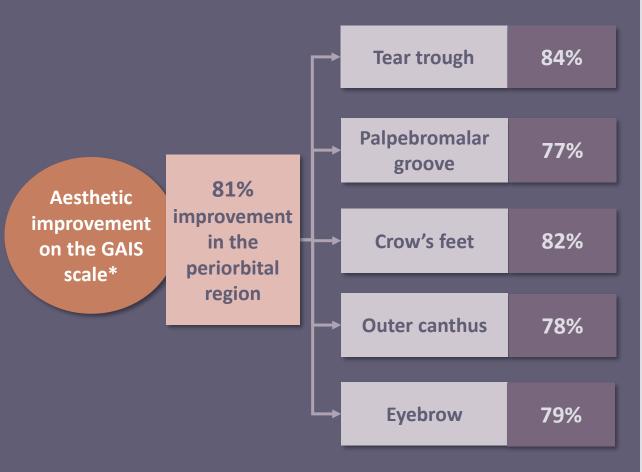




Most of the subjects required just one treatment session with Redensity 2, with only 19% requesting touch-ups



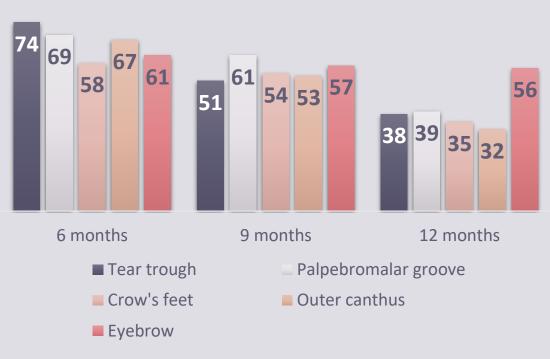
# Redensity 2 provided significant aesthetic improvement in the periorbital region



<sup>\*</sup>Proportion of subjects deemed "improved" or "much improved" on the GAIS scale by principal investigator and subject, at **29-153 days post-treatment or directly after injection** 



Performance of Redensity 2 was demonstrated up to 9 months, and was still satisfactory at 12 months for 1/3 of the subjects



Proportion of subjects deemed "improved" or "much improved" on the GAIS scale by principal investigator and subject, at different timepoints





# Most patients were satisfied and would recommend treatment with Redensity 2 in all periorbital indications

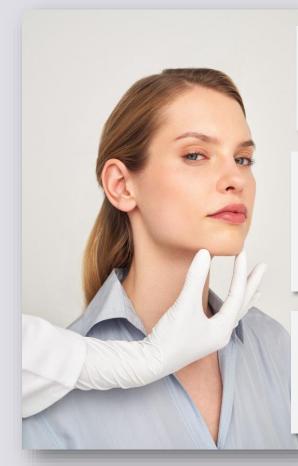




On average, **70%** of the subjects associated "natural looking" with their appearance after treatment, while **20%** used the word "rejuvenated"







#### **Injection site pain**

- Pain experienced by subjects after injection was deemed mild to moderate
- Pain intensity decreased drastically for all subjects by the end of consultation

#### Other common treatment reactions (CTRs)

- All CTRs reported by the investigator\* immediately after injection were deemed mild or moderate
- Bruising and swelling were the most frequent CTRs

#### **Adverse events**

Only two subjects experienced device-related adverse events (filler migration and skin oedema); both complications were rated moderate and were resolved without sequelae

As observed with PMS survey findings, RWE from a prospective observational registry confirmed the good safety profile of Redensity 2 in the whole periorbital region



### **Conclusions**

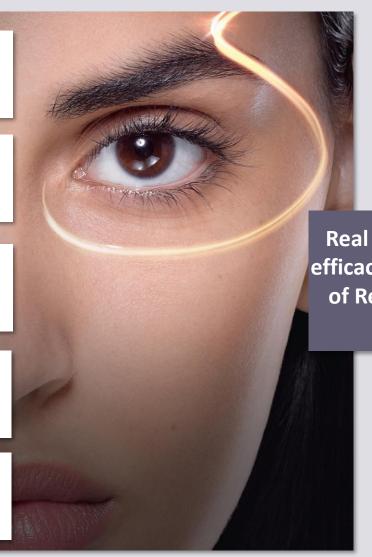
Redensity 2 is an HA-based dermal filler with specific properties that make it the **treatment of choice for the under-eye circles**, including the tear trough<sup>2,8-10</sup>

Observational evidence<sup>11-14,15</sup> confirmed the **tear trough as the main indication treated with Redensity 2**, but it also showed its use in **other periorbital indications** 

Almost all injectors were satisfied with initial treatment, and most of the subjects required only one treatment session with Redensity 2

RWE analysis confirmed the **effectiveness**<sup>15</sup> **and good safety profile**<sup>11-14,15</sup> of Redensity 2 in both the **tear trough** and the remaining **periorbital indications** 

Most of the patients were satisfied with Redensity 2 and would recommend this treatment in the periorbital region<sup>15</sup>



### **Perspectives**

Real world-evidence supports the efficacy, safety and the potential use of Redensity 2 to treat the whole periorbital region

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