2.PMCF study PMCFHS2021 – multicenter at 9 centers in the Czech Republic

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Classification criteria:	Hospital in Frýdek-Místek, MUDr. Martin Bílek Hospital with Polyclinic Karviná-Ráj, MUDr Veronika Suralová University Hospital Brno, Burns Clinic, MUDr. Michaela Fiamoli Medical centrum Prostějov, MUDr. Petr Šišma Regional Hospital T. Baťa, Zlín, Neonatal Department, MUDr. Josef Macko Surgical ambulance Březnice, MUDr. Jan Kopačka Surgical ambulance Jaroměř, MUDr. Miroslav Matoušek General practitioner for children and adolescents, Chrudim, MUDr. Iva Cibulková Surgical department Domažlice, MUDr. Ladislav Ouřada

Study conclusion:
A total of 319 monitored subjects were included in the study.
Subjects demography:

Gender	Number of subjects
Woman	168
Man	147
Total	**315**

Distribution of study subjects by age:

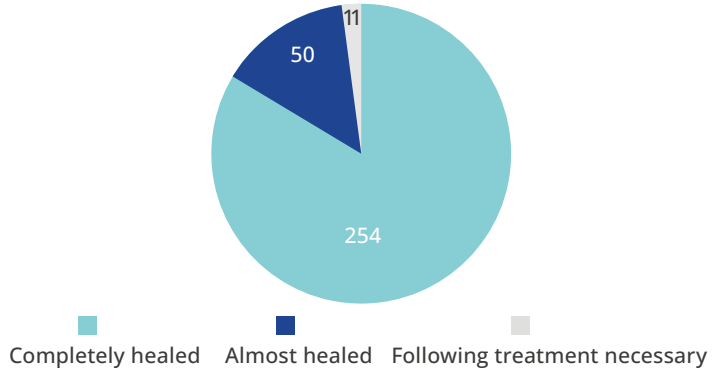
Age group	Age (year)	Number of subjects
newborns	0-29 days	23
infants	> 29 days and ≤ 1	3
toddlers	> 1 and ≤ 3	5
kids	> 3 and ≤ 15	13
adolescents	> 15 and ≤ 18	9
adults	>18	262
	Total	**315**

Distribution of study subjects according to indications.

Diagnosis	Number of subjects
Cuts, lacerations, lacerations	71
Abrasions, torn skin, blisters	80
Dermatitis, welts	28
1st and 2nd degree burns	43
Postopertaive wounds	77
Others	20
Total*	**319**

**2 diagnoses were determined in 4 patients*

Wound healing according to exit examination.



A total of 254 patients had a fully healed wound at the end of monitoring, in 50 subjects the doctor assessed that the wound was almost healed with a certain prognosis of recovery. In only 11 subjects, which is 3.5% of the total patient population, the wound was assessed as non-healed and thus requiring further treatment. All 11 subjects were classified as adults. 1 subject withdrew from the study. However, according to the doctor's assessment, this deterioration was not related to the application of MD.

Based on the obtained results, it can be assessed that **HemaGel® SPRAY** not only supports soothing the wound area, but it also plays an important role in ensuring a smooth course of healing without complications, when even in subjects who, upon entering the PMCF, do not show redness around the wound, and thus the development of inflammation, this condition is maintained throughout the healing period.

Overall, it can be determined from the obtained results that the administration of the medical product does not negatively affect the pain of the injury, thanks to the spray form of MD, there is no mechanical irritation of the wound during the application itself.
By its action, MD prevents the development of inflammation in the wound, which is subsequently manifested by increased pain. Based on the obtained data, it was confirmed that MD is largely involved in reducing the pain of injuries during healing.

In the study, **children between the ages of 0 and 18 were also monitored**, in whom administration of MD and monitoring within the study was carried out based on the informed consent of the legal representative and in accordance with the current instructions for use, where it is stated that the application in children is recommended after consultation with a doctor.
In newborns, the medical device was applied for three types of diagnoses, in 11 cases it was the treatment of the umbilical stump, in 3 cases, it was the treatment of nappy rash and dermatitis, in 8 cases it was the treatment of abrasions and in one case, a newborn was being treated for a laceration/cut/ wound.

After the end of the treatment, the injury was evaluated as **fully healed in 21 cases**. Only in **2 cases** was the condition of the wound assessed at the end of the study as **almost healed with a certain prognosis of recovery**. In both cases, it was a nappy rash in the area of the buttocks, the treatment was thus compromised by wearing diapers, a humid environment in the case of an unchanged diaper for a long time, and in general the necessity of rewrapping, and thus mechanical irritation of the injury and rubbing of the applied product on the material.

The positive result is that even at the end of the study, the area around the wound was calm in all cases, and it is thus clear that the product did not cause irritation or any other allergic reaction. No adverse events or complications were recorded in any case. For all monitored subjects, the legal representatives rated the application of the device as easy. In all cases there was a reduction in pain.
A total of 22 children between the ages of 4 and 18 were included in the study. No adverse events or complications occurred in any of the subjects. The reduction in the level of pain in these patients was in 95% of cases.

The total number of cases of **I. and II.a degree burns** in the study was 43. The average healing time for patients with burns was 10 days, median healing time was 8 days. **Burns were fully healed in 35 patients and with an almost certain prognosis of recovery in 8 patients.** There was no worsening of the wound or side effects in any patient. Based on these results, the treatment of I. and II.a degree burns with the medical device **HemaGel® SPRAY** can be evaluated as effective and safe.

Patient compliance during treatment means cooperation and willingness of the patient to cooperate in accordance with the treatment procedure. This is largely influenced by whether the treatment is pleasant and simple to use for the patient. During the evaluation, the patient recorded subjective feelings during application according to Table VIII.

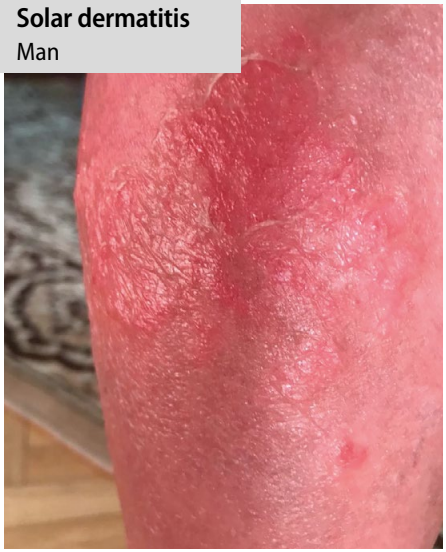
Patient´s feelings after application promptly	☐ Unpleasant, burning, stinging	☐ NO negative reaction	☐ Others

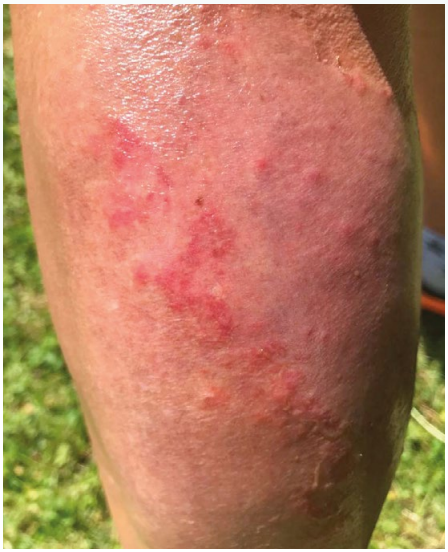
313 patients from total 315 declared comfortable and smooth application of the Medical device. Only 2 subjects perceived the administration of the medical device as complicated.
This is less than one percent of patients. One of these subjects was a premature neonate who was hospitalized and treatment was complicated by fungal skin disease of the buttocks. Nevertheless, the treated wound was evaluated as fully healed after the completion of the ZP treatment. Complications were not directly related to ZP application. The second subject was an adult patient who, on the 4th day after the start of the treatment, reported blockage of the nozzle and the impossibility of applying the spray. In the instructions for use, it is recommended to mechanically clean or wash the spray nozzle with water in the event of a nozzle blockage, and therefore in the second case it was a failure to follow the recommended use procedure.

One patient appreciated the possibility of hygienic application using a spray dispenser, i.e. without the need to touch the wound with fingers or other tools.
One patient found the application of ZP to have a pleasant cooling effect.

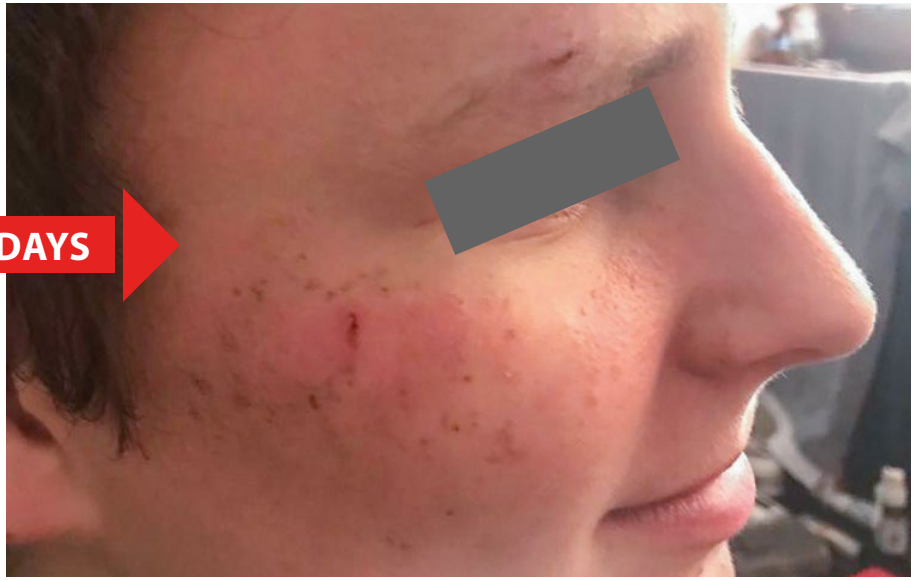
The spray application and the ergonomics of the packaging of the medical device can thus be evaluated as suitable and comfortable for the intended purpose and target group of patients.

Solar dermatitis
Man





Abrasions from a fall on a scooter
Boy 14 years old



HemaGel®
SPRAY

We look forward to working with you.

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