Cacicol20, a New Matrix Therapy Device Improves Resistant Corneal Ulcers and Keratitis

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PURPOSE: to evaluate tolerance and safety of CACICOL20 a new ophthalmic device in a pilot study on chronic corneal ulcers and severe chronic keratitis with very long term resistance to usual treatments, these patients been their own controls. **RATIONNAL:** CACICOL20 contains large biopolymers engineered to replace heparan sulfates destroyed in injured cornea by specifically binding to matrix proteins including growth factors, that they protect from proteolysis occurring after a lesion. This restores extracellular matrix microenvironment back to its original architecture and cells recognize intial matrix scaffold organization. **METHODS**: Eleven eyes from ten patients from patients with severe keratitis or painful corneal ulcers rating over 50 on the visual analog pain scale (VAS). All had undergone unsuccessful treatments lasting from 25 to 5 years for 8 patients and 24 to 6 months for the last 3 patients. CACICOL20 ophthalmic device was instilled once a week over 1 month. Tolerance and efficacy were judged on subjective criteria based on pain evaluation and functional inconvenience and on objective clinical criteria through the study. **RESULTS**: Tolerance was excellent both locally and generally. A noticeable analgesic effect was observed increasing with time and instillations, but pain increased in the majority of cases after treatment ended. The mean VAS at the inclusion was 72.73 +/- 7.86, it decreased significantly with the first drops of treatment. After 1 month, it was 32+/- 15.49, and increased after the end of the treatment, confirming the link between the effects observed and the treatment. Efficacy on keratitis was moderate but with an overall tendency toward improvement. The initial Oxford Score was 3.37 +/- 1.06. After 1 month, it decreased significantly to 1.57 +/- 0.97 and then it rose again after the end of the treatment. As for corneal ulcers, of the five cases included, four healed during the protocol. Two reversed when the treatment stopped, two healed without reversion at the last follow-up visit. **CONCLUSION:** CACICOL20 ophthalmic device is the first matrix therapy product available in Europe in ophthalmology and provides an innovative solution for unresolved pain and corneal surface healing problems.