



## Clinical White Paper

The care of skin wounds and skin infections is a chronic problem routinely encountered in ambulatory and institutional (hospital and long term care) health care settings. Moreover, an aging population that is exceptionally prone to pressure ulcers and chronic wounds that contribute to loss of functional capacity, results in substantial utilization of health care resources at an increasing cost. *ONE*, is an aqueous, highly purified solution of castor oil, magnesium, sodium and silicate with “detergent-like” properties and with the ability to maintain a sterile environment in the wound area. *ONE* is formulated as gels and sprays and includes; *ONE for Cuts and Burns*, *Little ONE for Baby Bums*, *ONE for Sunburns*, *ONE-Plus Wound Care* and *ONE Pet Treatment*.

The *ONE* family of products has been exposed to rigorous testing in clinical settings in both North America and China. The efficacy of *ONE-Plus Wound Care* with respect to chronic wounds and pressure ulcers was investigated in 16 nursing homes in Ontario, Canada. Studies were conducted in male and female subjects ( $n = 38$ ) and all subjects were refractory to conventional treatments such as antibiotic ointments, standard dressings, oral antibiotics and wet/dry dressings as well as combination therapies. The majority of wounds (75.5%) in the study group were more than 4 months old at the initiation of *ONE-Plus* treatment with 14.3% between 1 and 4 months old and 10.2 % of wounds less than 1 month old. Wounds were classified as Stage II (65.3%), Stage III (16.3%) and Stage IV (14.3%) and evaluated as “moderately” or “significantly” healed. 75.5% of Stage II wounds greater than 4 months old, were either “moderately” or “significantly” healed following treatment with *ONE-Plus*. Wound and pressure ulcer healing time was on average  $33.2 \pm 15.4$  days for moderately healed Stage II,  $46.1 \pm 21.3$  for significantly healed Stage II,  $65.3 \pm 27.6$  days for moderately healed Stage III-IV and  $40.4 \pm 15.2$  days for significantly healed Stage III-IV wounds. Not only were healing times remarkably improved, a cost minimization study demonstrated that the cost for treatment with *ONE-Plus*, was 80.2% less for “moderately” healed wounds and 75.5% less for “significantly” healed wounds when compared to conventional treatments.

Clinical studies were conducted at two sites in China: 1) the Department of Burns and Plastics at People’s Hospital of Gansu Province and 2) the Department of Burns and Plastics at Lanzhou General Military Hospital. Studies were conducted in male and female subjects with shallow and deep second degree ( $2^0$ ) burns as well as subjects with deep third degree ( $3^0$ ) burns with granulation. At the People’s Hospital of Gansu Province, *ONE-Plus* was compared to Chinese Gromwell Oil (CGO) in 20 subjects with shallow  $2^0$  burns, 30 subjects with deep  $2^0$  burns and 12 subjects with  $3^0$  burns. Improvement was shown in subjects with shallow and deep  $2^0$  burns, healing time was significantly decreased to  $5.7 \pm 2.2$  days compared to CGO at  $8.3 \pm 2.9$  days and  $12.8 \pm 3.6$  days compared to CGO at  $18.3 \pm 4.9$  days ( $p < 0.05$ ), respectively. A significant improvement in time to wound dryness was noted with *ONE-Plus* treatment with dryness detected at  $27.1 \pm 5.3$  hours vs.  $42.5 \pm 9.6$  hours ( $p < 0.01$ ) for shallow  $2^0$  burns and  $34.7$

$\pm 6.6$  hours compared to CGO at  $48.6 \pm 7.9$  hours ( $p < 0.01$ ) for deep 2<sup>o</sup> burns. Pain relief was improved with *ONE-Plus* for subjects with shallow and deep 2<sup>o</sup> burns. Shallow 2<sup>o</sup> burn subjects experienced relief at  $67 \pm 39$  seconds and deep 2<sup>o</sup> burn subjects at  $82 \pm 42$  seconds compared to no effect with CGO. Subjects with 3<sup>o</sup> burns ( $n = 12$ ) demonstrated improved skin surface for grafting, wound secretions as well as pain relief with *ONE-Plus*.

Studies conducted at Lanzhou General Military Hospital focused on treatment with *ONE-Plus* compared to Chuang Kou Jing (CKJ) with assessment of healing times of shallow and deep 2<sup>o</sup> burns, as well as chronic ulcers. For subjects with shallow 2<sup>o</sup> burns ( $n = 28$ ) healing times were  $11.04 \pm 1.62$  days with *ONE-Plus* compared to  $11.25 \pm 1.78$  days with CKJ. Healing times were significantly different in subjects with deep 2<sup>o</sup> burns ( $n = 12$ ) with *ONE-Plus* treated burns at  $19.33 \pm 1.57$  days vs.  $21.39 \pm 1.65$  days for CKJ treatment ( $p < 0.05$ ). Chronic ulcers in 3 subjects were healed in  $29.44 \pm 5.65$  days. Both treatments demonstrated similar outcomes with respect to wound secretion, appearance upon healing and pain relief. Remarkably, *ONE-Plus* subjects demonstrated superior resolution of scarring and debridement of necrotic tissue.

In North America, antimicrobial, mutagenesis screening and toxicity studies have shown that *ONE* has anti-microbial properties, does not irritate, is non-toxic topically and orally and does not demonstrate mutagenic activity. In vitro studies have shown that *ONE* enhanced cell growth (dose dependent) and increased viability of keratinocyte (human skin cell) growth. Skin sensitivity, toxicity and allergy tests were also conducted in China at the Pharmacological Laboratory of the Gansu Drug Testing Institute. These analyses also demonstrated that *ONE* is non-toxic, non-allergenic and does not irritate intact or damaged skin.

In conclusion, the *ONE* family of products has been shown to have the ability to significantly reduce healing time, minimize infection, promote healing and improve or eliminate pain in burn subjects. Moreover, *ONE-Plus Wound Care* is an effective agent for the treatment of chronic ulcers and pressure sores, that are refractory to conventional treatment, with the additional benefit of reduced cost of treatment for these increasingly frequent medical conditions.

*ONE* products have demonstrated, in international clinical settings, the capability to maintain a sterile wound healing environment, to control infection due to anti-bacterial properties as well as the ability to relieve pain and stimulate human skin cell growth.

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### References:

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