Cooling Power of the ThermoSuit System

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The ThermoSuit System is the only FDA-cleared patient cooling device that cools using direct liquid contact with the patient. This approach has been proven to be the most efficient means to reduce core body temperature, and is very safe as well. This report discusses some of the published data related to this topic, and provides data which verify the superiority of this cooling method [LRS Technical Report, August 2013).

Medical interest in the area of patient cooling methods has dramatically increased in recent years, as studies have reported significant benefits for prompt administration of therapeutic hypothermia [eg. 1,2,3]. Likewise, the need to aggressively treat severe hyperthermia demands the use of a powerful and safe cooling method [4].

Several methods are available for cooling the body by surface cooling. Three popular methods are conventional water-filled cooling blankets (such as offered by Cincinnati Sub-Zero), gel-faced cooling pads (Medivance Arctic Sun), and direct contact of the skin with flowing ice water, as is provided by the Life Recovery Systems ThermoSuit® System. Clinical studies investigating these methods have yielded data which enable direct comparisons of "**cooling power**". Cooling power provides a direct measure of the rate at which heat is removed from the body, which directly impacts the speed of core temperature reduction. It enables direct comparisons of the effectiveness of different cooling methods which may have been tested in patients with different starting temperatures and weights. The following report presents calculations and comparisons of the cooling powers of three cooling methods, and discusses some of the key factors which account for the differences in cooling performance.

For the purposes of this discussion, we will define cooling power in terms of the overall effect of the cooling method to reduce body core temperature as follows:

Cooling Power of Cooling Device

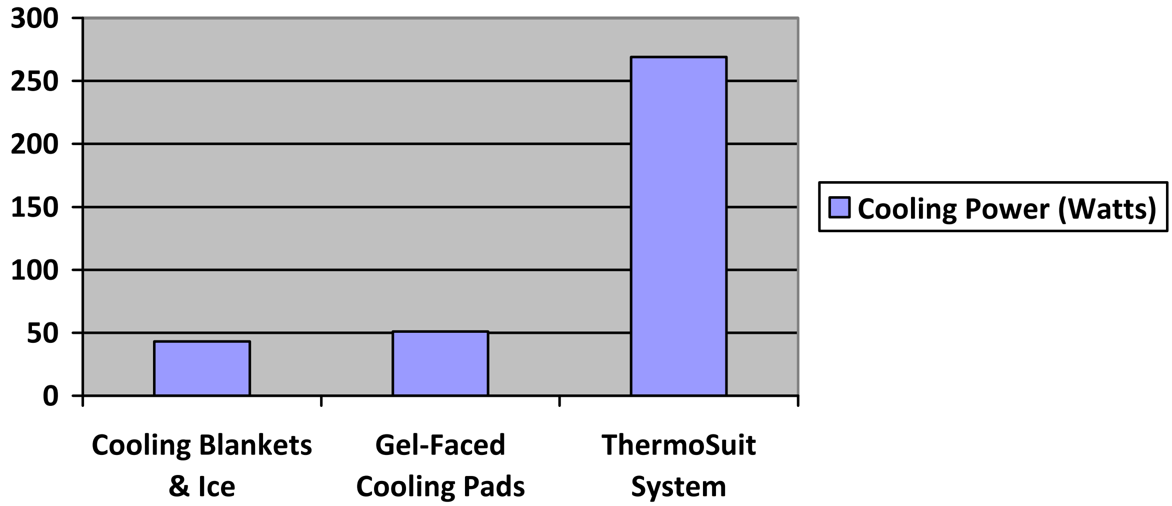
$$= \frac{\text{Body Heat Loss Caused by Cooling Device}}{\text{Cooling Time}}$$

$$= \frac{\text{Body Heat Capacity x Temp. Drop x Body Weight}}{\text{Cooling Time}}$$

If we assume 3470 J/Kg C° is the heat capacity of the human body [5], applying the above analysis produces the following results:

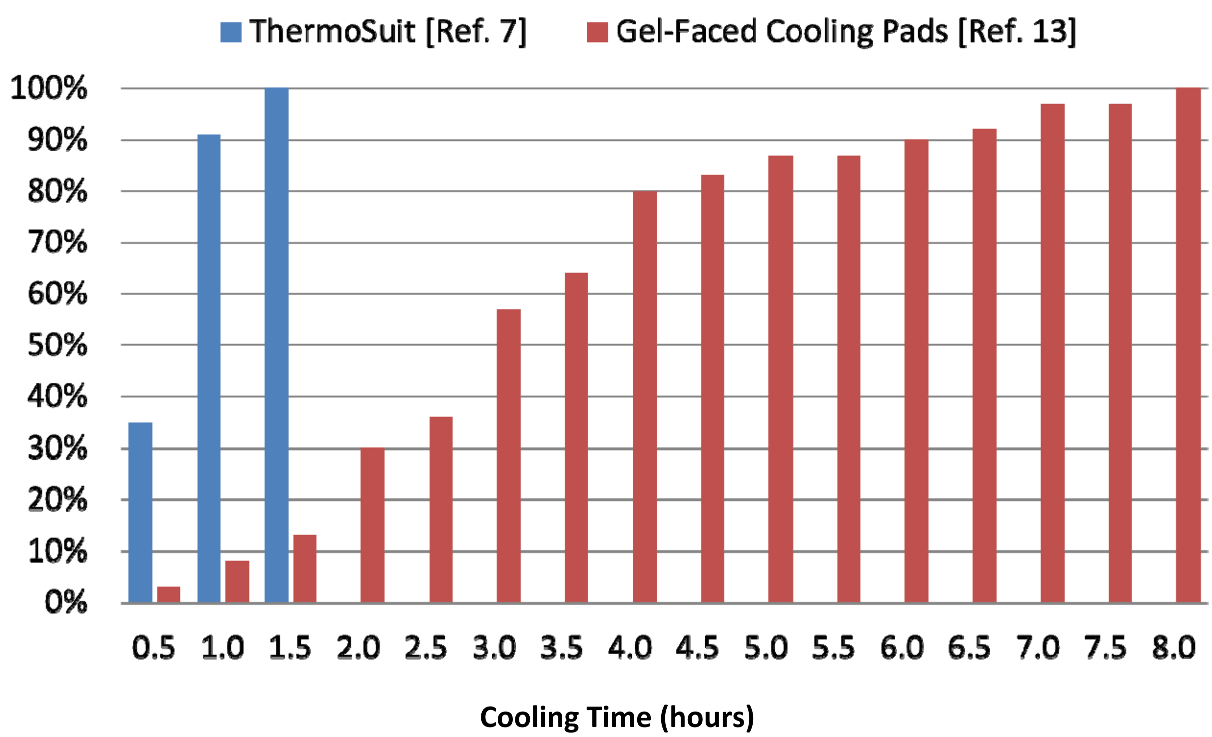
Cooling Device	Patient Temperature at Start of Cooling (°C)	Patient Temperature reduction (C°) to reach 34°C	Time to Cool Patient to 34°C (minutes)	Patient Weight (Kg)	Cooling Power (Watts [8])
ThermoSuit® System [7]	36.1	2.1	37	81.9	269
Cooling Blankets and Ice Packs [6]	36.0	2.0	244	91.0	43
Gel-Faced Cooling Pads [6]	36.0	2.0	190	84.0	51

The above results are plotted graphically below:



From the above analysis, it can be seen that **the ThermoSuit System has over five times the cooling power of cooling blankets and ice or gel-faced cooling pads**. This means that the ThermoSuit System produces a shorter cooling time in general, and more reliably enables the achievement of target temperatures. This performance advantage can also be seen from a comparison of cooling times from published clinical studies as shown below:

Cumulative Percentage of Patients Achieving Target Temperature Over Time



The above cooling power advantage of the ThermoSuit cooling device may seem surprising given the results previously reported by English and Hemmerling [9] comparing gel-faced cooling pads and cold water immersion. These authors reported comparable heat transfer coefficients for the pads and 10°C water immersion. However, the ThermoSuit System contacts approximately 90% of the body's surface area, giving it an advantage in terms of heat transfer area vs. the cooling pads, which typically only cover 40% of the body. Furthermore, the ThermoSuit System operates with water that is colder than 10°C (the ThermoSuit usually cools with circulating water at about 2°C). Clinical research by Proulx et al [10] demonstrated that colder water significantly increased the cooling rate of immersed human volunteers. This is in part due to the increased thermodynamic advantage of using colder water, but a physiological effect is also a factor: Proulx et al reported that only one of seven volunteers shivered when immersed in 2°C water, while six of seven shivered in 8°C water. Thus, the colder water suppressed the shivering response in most subjects. Correspondingly, this study reported that subjects in 2°C water lost heat approximately 50% more rapidly than those in 8°C water.

The act of intentionally reducing body temperature is a seemingly simple task, but in practice it can be challenging. The human body is exquisitely designed to maintain a relatively constant body temperature, and strong physiological countermeasures are set in motion if there is significant deviation from normal temperature (37°C). Surface cooling is a popular method to intentionally cool patients, either as a treatment for hyperthermia or to induce therapeutic hypothermia. However, the body's natural reaction a low skin temperature is to trigger cutaneous vasoconstriction, which drops blood flow to the skin surface and impedes heat transfer from the body core. An advantage of the cold water immersion technique is that cold water below 8°C counteracts this reflex and causes vasodilation of the skin, a physiologic response known as the hunting or Lewis reaction. This is most likely a result of a complete nervous block which occurs at a local temperature below 8 to10°C [14]. This vasodilation improves heat exchange between the skin and the core, and is yet another mechanism that contributes to rapid patient cooling with the ThermoSuit device.

If surface cooling is sustained and core body temperature falls below 35.5°C, the shivering response is typically activated, and this usually continues as cooling continues until a core temperature of 33.5°C is reached. This physiologic response dramatically reduces the ability of the body to be cooled. Shivering raises metabolic rate significantly and adds to the stress on the body. If the goal of cooling is to induce therapeutic hypothermia in a critically ill patient, a rapid cooling induction is desirable. "Rapid induction decreases the risks and consequences of short-term side effects, such as shivering and metabolic disorders" [12].

The LRS ThermoSuit° System*: Provides the highest noninvasive patient cooling power available.*

In summary, the ThermoSuit System has a cooling power over five times as great as conventional cooling blankets and gel-faced pads. This is due to a highly efficient heat exchange mechanism that minimizes shivering and cutaneous vasoconstriction. The ThermoSuit System should be considered when rapid patient cooling is desired.

<u>FDA-Cleared Indications for The LRS ThermoSuit System:</u>

Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients.

<u>CE and Health Canada – Cleared Indications for the LRS ThermoSuit System</u>:

Temperature reduction in patients where clinically indicated, e.g., to induce hypothermia in patients to preserve cardiac and brain function in victims of cardiac arrest, stroke, heart attack, traumatic brain injury.

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