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A Double blind comparative study to determine the efficacy of a 25% urea cream vs. a 10% urea cream, in treating anhydrosis.

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the BSc (Honours) degree in Podiatry

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Acknowledgements

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I would also like to acknowledge Mr S Baird, Mrs C, Skinner and Jamie Frankis for all their understanding, support, help and encouragement within this period. I especially have to thank Jamie for being a statistical genius and for his confidence boosting sessions.

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Introduction

The terms anhydrosis and xerosis are used interchangeably to describe a skin condition which presents as dry, rough and scaly with possible presence of reddening, cracking or itching (Flynn et al, 2001). For the purpose of this project, the term anhydrosis will be applied. Anhydrosis can affect all age groups and features regularly within the podiatrist's clinical environment. The skin may also present as less flexible than normal, contributing to the irregular feel which is usually rough and uneven to touch (Flynn et al 2001, M.Loden, 2003).

The likelihood of anhydrosis developing increases with age, exposure to chemicals, micro organisms, low environmental temperature and humidity and any physiological changes that alter the circulatory supply to the lower limbs (Hau Trung Pham 2002, Loden 2003). Medical conditions in which anhydrosis may present as a consequence include autonomic neuropathy in association with diabetes, hypothyroidism, peripheral vascular disease and systemic sclerosis (Baird et al, 2002).

To establish how anhydrosis affects the stratum corneum it is imperative to look at the normal structure and function of the most superficial layer of the skin. The barrier function of the skin prevents foreign bodies and substances entering the stratum corneum, which is impermeable except for a small amount of water loss. This small but vital flux of water is termed trans-epidermal water loss (TEWL), which enables the outer layers of the stratum corneum to remain, hydrated retaining the flexibility, and allowing maturation and desquamation of the corneodosomes (Henrich et al 2003, Madison 2003, Rawling & Harding 2004, Harding 2004). According to Jennings et al (1998) the stratum corneum must retain at least 10% water for it to remain soft and pliable.

It is widely recognised that hydration is maintained within the stratum corneum due to three main factors:

- Intracellular lipids, these lipids are organised in an orthorhombic gel which enables them to provide an effective barrier to the passage of water through the tissue, reducing trans-epidermal water loss (TEWL).
- The unique interlaced brick and mortar structure of the stratum corneum layer and its corneocyte envelopes creating a tortuous path preventing a high TEWL.
- The natural moisturising factor (NMF) which is critical to the skin condition and water binding in the outer layers of the stratum corneum consists of a natural mix of amino acids, urea and electrolytes (Rawlings & Harding 2004, Henrich et al 2003)

It is well documented that in dry, anhydrotic skin there is a loss of moisture from the stratum corneum and intercellular matrix due to a high TEWL (Hau Trung Pham, 2002). The desquamation process is impaired and the corneodosomes are not degraded efficiently, therefore the corneocytes accumulate on the skin surface, thus giving the recognised dry, flaky appearance of anhydrosis (Hau Trung Pham 2002, Henrich et al 2003, Jennings et al 2002).

There seems to be a general agreement that the treatment of anhydrosis should be aimed at restoring the water balance of the epidermis (Baird et al 2002, McCallion & Li Wan Po 1994). The aspects of treating anhydrosis address three main areas, replacing the water content and maintaining hydration to alleviate the symptomatology and control the keratinisation to reduce scaling (McCallion & Li Wan Po 1994, Jennings et al, 2002)

It is acknowledged that the skin's hydration levels can be increased with regular use of a moisturising agent (Paepe et al), however this is not a new concept and in fact dates back to Egyptian times (Flynn et al, 2001). Moisturising agents are compiled of different components all of which have individual properties and affects on the skin; these components are divided into three main categories: an occlusive, humectants and emollients.

An occlusive is an oily substance, usually water in oil emulsions which provide a greasy layer over the stratum corneum, thus preventing a high TEWL and therefore increasing the levels of hydration (Flynn et al, 2001). However, humectants have hygroscopic properties allowing them to be absorbed into the skin, increasing the content of water in the site by attracting water from the dermis level of the skin therefore increasing the stratum corneum hydration levels (Rawlings et al 2004, Andersson & Lindberg, 1999; Jennings et al, 1998). Emollients have hydrophilic properties and act primarily on the skins surface, thus making the stratum corneum soft, supple and flexible (Jennings et al, 1998). This result is achieved by filling in the spaces between the dry scales with oil droplets; however they are not generally occlusive unless applied heavily at regular intervals (Lynde, 2001)

Examples of the components of moisturisers are presented in table 1.

Table 1 **Moisturisers and their components**

Component in moisturiser	Mechanism of ingredient	Examples	Side effects
Occlusive	Physically blocks trans- epidermal water loss	Petroleum, Lanolin, Mineral oil, Silicones, zinc oxide	Messy, can be cosmetically unacceptable
Humectants	Attract water to stratum corneum for dermis level of the skin	Glycerine , urea, sorbital	Irritation can occur(urea, lactic acid)
Emollients	Smooth skin by filling spaces between skin flakes with droplets of oil.	Cholesterol, Squalene, Fatty acids	Not always effective

Source adapted from Lynde, (2001)

Urea is a substance that penetrates the skin easily and is a molecule which is found in human tissues, blood and urine and is also a major constituent of the skin's NMF (Serup 1992, Baird et al 2002). As a humectant, urea improves the degree of hydration in the skin by increasing the water uptake from the dermis level of the skin and enhances the stratum corneum water–binding capacity (Loden 1996, Loden et al 2001, Jennings et al 1998). At higher concentrations (20-30%) urea also has a mild keratolytic effect where it disrupts the hydrogen bonds and epidermal proteins (Lynde 2001, Loden 1996). It is widely acknowledged that a moisturiser containing urea

improves the skin hydration level by increasing the water content of the stratum corneum (Serup 1992, Duvalet al 2003). According to Loden (1996) urea proved to influence both TEWL and increase the degree of hydration at the stratum corneum.

Previous studies have concluded that the treatment of anhydrosis should be regular use of a moisturising agent that increases the skins hydration levels and prevents TEWL (Baird et al 2002, Corcorran & Flynn 2001). The project compares the efficacy of two creams, one cream containing 10% urea and the other cream containing 25% urea in the treatment of anhydrosis. Therefore, the main aims of the project are to demonstrate whether the urea creams significantly improve hydration and elasticity levels in the stratum corneum and to determine whether the higher concentration of the urea produced significantly greater effects.

Methodology

Ethical approval was obtained from both Glasgow Caledonian University and South Glasgow hospitals NHS trust for a double blind paired comparison study evaluating the effects of a 25% urea cream on one foot and a 10% urea cream on the other foot, over a period of six weeks in participants with mild to moderate anhydrois. The severity of the anhydrosis was assessed using an adapted anhydrosis severity scale and corresponding pictures of the scale , presented by Rogers et al,1989 cited in Jennings et al 1998 (Table 2)

Table 2: Anhydrosis Severity Scale

Severity	Severity Scale Score	Description
Mild	0	Normal Skin
	1	Dusty appearance, occasional minute flakes.
	2	Generalised dusty appearance, many minute flakes.
Moderate	3	Defined scaling with flat borders
	4	Well defined heavy scaling with raised borders, shallow fissures
Severe	5	Large scale plates, fissures
	6	Large scale plates, deep erythemtous fissures

Source adapted from Rogers et al, (1989)

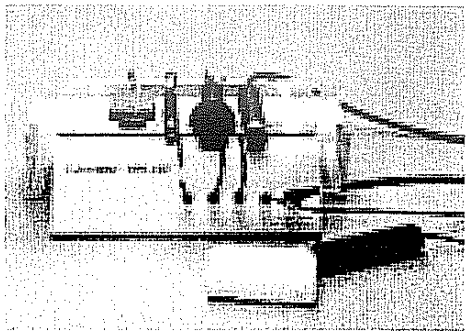
The sample comprised of 37 outpatients (7 male, 30 female) who attended for routine treatment at the Podiatry Department of Southern General hospital between September 2004 and January 2005. The subject selection criteria included participants presenting with bi-lateral anhydrosis scoring between 1 to 5 on the Anhydrosis severity scale (visual appearance only). Participants whom had any other previous dermatological conditions or had a known hypersensitivity to urea were excluded from the project.

After the visual selection of the participants, the project was explained verbally to the participants. The participants were then supplied with an information sheet explaining the project aim and what would be required of the project. They were then given the opportunity to ask the researcher any questions regarding the project before verbal and written consent were obtained. The participants were given an appointment to return one week later to commence the study, during this time the participants were asked to refrain from applying emollients or moisturising creams to their feet.

On the first visit, their baseline hydration and baseline elasticity levels were recorded using the Cutometer MPA 580 (elasticity) and the Corneometer CM 825 (hydration) and its attached probes. The measuring principle of the Cutometer MPA 580 is based on the suction method, negative pressure is created within the device and the skin is then drawn into the aperture of the probe. The penetration depth is determined by a non- contact optical measuring system.

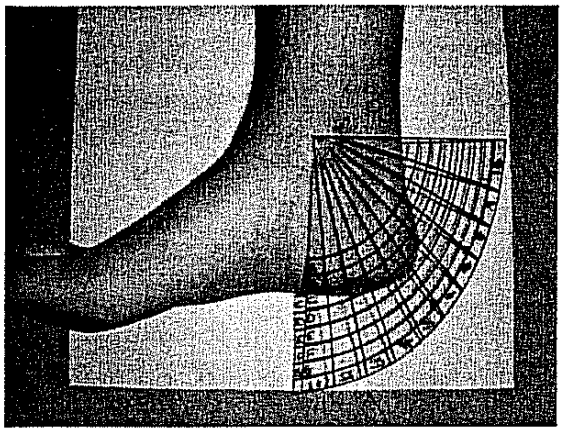
The measurement of skin moisture is based on the internationally recognised corneo-meter method, which is a capacitance method and is when skin moisture is based on the completely different dielectric constant of water and other substances. The measuring capacitor shows changes of capacitance according to the moisture content of the skin. "The corneo-meter has gained worldwide acceptance as an efficient instrument to measure the water content in the stratum corneum under a great variety of experimental conditions" (Henrich et al, 2003).

Picture 1: **The Cutometer MPA 580**



To ensure intra- tester reliability the site of the measurement was recorded using an acetate instrument that was placed on the participants' medial or lateral malleoli, and curved round the plantar surface of the foot. The instrument was graphed and each area of the instrument was identified by a letter and a number, each area also had a small hole to enable a mark to be placed on the participants foot using an ink pen (see picture 1).

Picture 1: Acetate Measuring instrument



This enabled the exact site of measurement to be recorded, measurement values were obtained from as near as possible the same site during all visits. Subsequent hydration and elasticity measurements were recorded at two weekly intervals with a final reading recorded at week six.

The different percentage urea creams were dispensed to the subjects in 125-gram tubes, which were labelled left and right foot, respectively by an outside source. The participants and the researcher were unaware which cream had been dispensed in each tube. The researcher applied the first application of cream to the participants' feet in order to demonstrate the correct method and amount to be applied, a written protocol regarding the creams applications was also given to participants.

The participants were advised to apply the cream once per day to the plantar aspect of the foot using the right hand to apply the cream to the left foot and vice versa to avoid any cross contamination of creams. The amount to be applied to each foot was half an index finger and this was to be spread liberally across the plantar surface of the foot. The compliance of participants was measured by weighing of their tubes of cream on their two weekly visits. If participants were adhering to the written instructions, they should have applied approximately 25grams of each cream between visits. The participants to gain their opinions on the effectiveness, absorption and satisfaction on each cream completed a post -project questionnaire.

To ensure reliability and repeatability of the measuring results it is of utmost importance to create suitable conditions for skin measurements to be recorded. The conditions that were controlled were:

* In advance the Cutometer MPA 580 and its attached probes were calibrated by the supplier.
* Climatic conditions- The temperature and humidity were managed using an attached sensor probe. The temperature ranged between 20°c -25°c with humidity ranging between 40- 60%.
* All measurements were recorded in the same room ensuring the same lighting conditions each time.
* All measurements were taken by the same-trained researcher and 10 seconds time allowed in-between each individual measurement to prevent the probe causing an occlusive effect on the skin.
* Each measurement was taken three times on the same area and the average measurement recorded.
* All measurements were taken from the patient 15 minutes after entering the room to allow the participant to acclimatize.

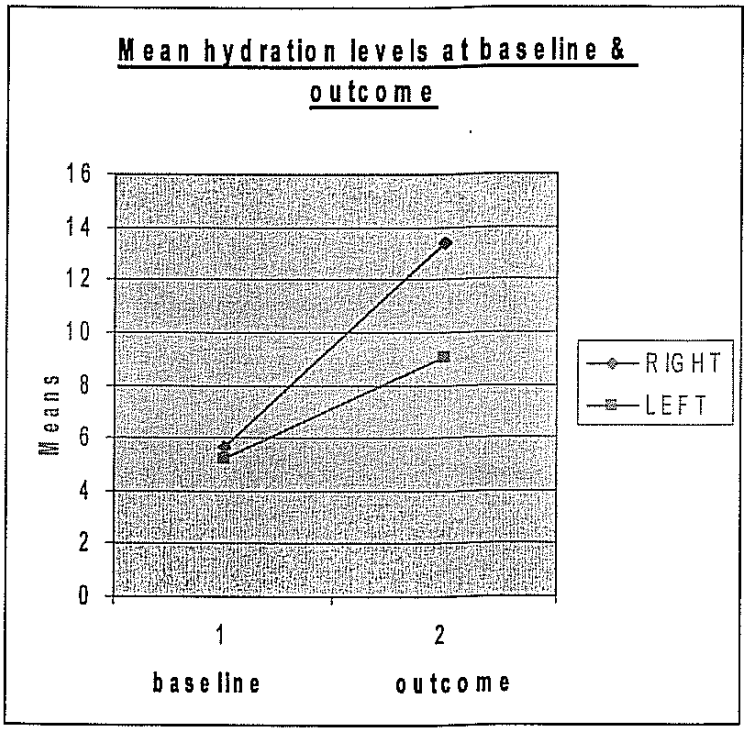
Results

The study originally consisted of 37 participants, however due to various reasons the number of participants that completed the study through to week six was 26. Following the completion of the study, it was revealed that the tube labeled 'right' contained 25% urea cream and the tube labeled 'left' contained 10% urea cream.

Data was anaylsed using a two way repeated- measures ANOVA with both treatment stage and urea concentration as within participant factors. The main effect of using cream was significant ($F_{(1,25)} = 103.995$, $p = 0.000$), that is both the 10% and 25% urea creams resulted in an increase in hydration levels of the skin. The strength of the cream was also significant ($F_{(1,25)} = 13.326$, $p = 0.001$), meaning that the 25% urea cream was more hydrating than the 10% urea cream. However, this effect alone does not take into account the potential baseline differences. Therefore, this study is most

interested in the interaction between the baseline readings and the outcome readings and the difference in the percentage of urea in the creams. There was a significant interaction between baseline and outcome and the cream strength ($F_{(1, 25)} = 15.338$, $p=0.001$). As can be seen in graph 1, although both creams significantly increased skin hydration, the significant interaction suggests that the 25% urea cream increased hydration levels significantly more than the 10% cream. In conclusion, although the 10% cream improved hydration levels, the 25% cream was significantly better.

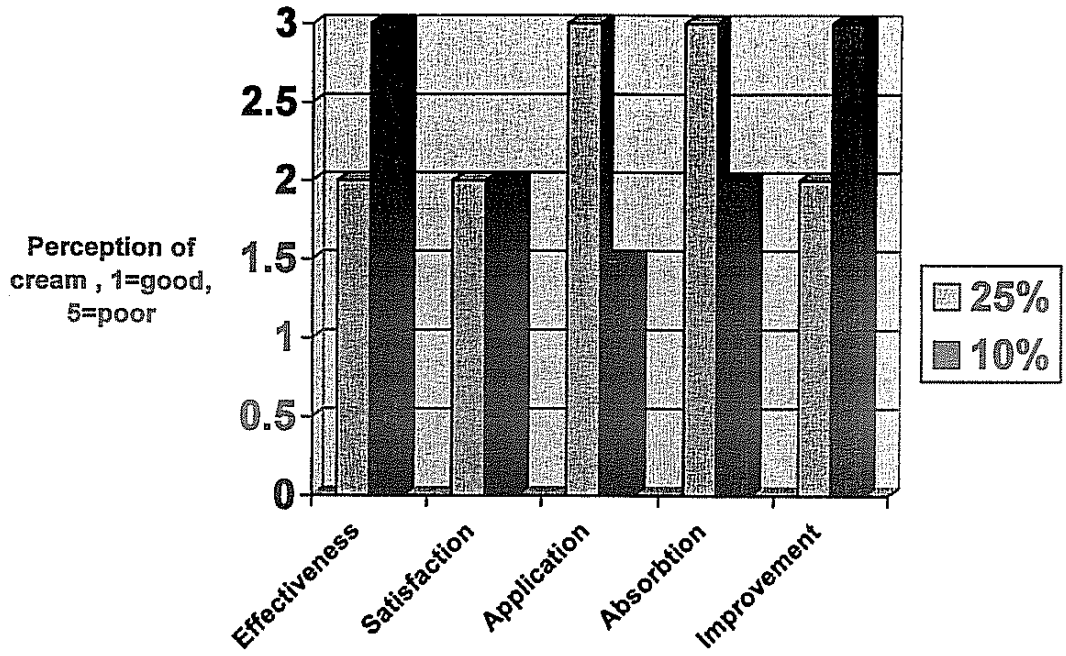
Graph 1: Hydration levels of the skin at baseline and outcome



The post study questionnaire looked at the participants' perception of both the 10% urea cream and the 25% urea cream. Here, the data was not normally distributed in each case. Rather than transforming the data as employed in the previous test, non-parametric analysis was employed since the data was technically ordinal. Therefore Wilcoxon Signed- Ranks tests was performed. The results concluded that there was no difference in the participants' perception of the effectiveness of the 10% urea cream compared to the 25% urea cream ($p = 0.145$) and in the participants satisfaction with the cream ($p = 0.654$). However, there was a difference in the participants perception of the application of the creams ($p =0.001$), absorption of the creams ($p =$

0.000), in both cases the 10% cream was preferred. However crucially, analysis suggested that participants perception of improvement of creams (p=0.046) was significantly better in the 25% cream. Thus concluding that the participants' perception of the 10% urea cream was that it was easier to apply and was absorbed more effectively. However, they thought that the 25% urea cream made the most improvement to their dry skin. (Refer to graph 2)

Graph 2: **Participants perceptions of the creams.**



Discussion

In this project, a significant difference in the hydration levels of the participant's skin was noted with the use of both the 10% urea cream and the 25% urea cream, however the 25% urea cream showed a greater increase. The results of this project are compatible with previous similar studies (Baird et al 2002, Loden et al 2001, Serup 1992, Loden 1996). It has been previously documented that urea in moisturisers can cause irritation to the skin (Lynde, 2001). Following the completion of this project there was no reported adverse reactions to the application of either cream.

It is recognized that this project was underpowered in terms of the number of participants recruited; participant compliance with treatment is one of the considerations that may have influenced the overall results. Even though applying a moisturiser to the feet seems a simple task 30% of participants failed to apply the cream as advised and therefore did not complete the project. There are other areas within the project for potential error in relation participant compliance. Such as whether the protocol for cream application was adhered to, the participant's footwear or hosiery choice and the frequency of washing of feet.

Potential errors exist due to research conditions and difficulty with interpretation of data from the Corneometer CM 825. Corneometer measurements are claimed to reflect the hydration status of the skin but can be influenced by other factors such as cream residue, the temperature and humidity of the research area and the positioning of the probe. The Cutometer instruction handbook advises that the humidity should be consistent and the temperature should remain between 20- 22 degrees in order that the measurements are not influenced. In previous studies, it is acknowledged that low humidity and temperature will cause an increase in TEWL and a decrease in the hydration levels, leading to a decrease in the stratum corneum hydration levels (Egawa et al 2002, Harding 2004). It is also understood that if the temperature and humidity is high then sweating may occur in the participant therefore causing the stratum corneum to be more hydrated. Egawa et al, 2002 confirm that a short exposure of around three to six hours to a low humidity environment would change the moisture content within the stratum corneum and the skin surface pattern. The patients in this study were only within the research environment for a maximum of 30 minutes; therefore, it is unlikely that the temperature and humidity of the room had an effect on their skin hydration levels. To ensure consistency of measurement the temperature and humidity should be kept within the recommended parameters.

The study commenced during the autumn and winter months, it is noted that in general skin is less hydrated in these months due to the low temperature and humidity in the winter months (Harding 2004, Nicander & Ollmar, 2000). The decrease in humidity and temperature effects the stratum corneum, reducing the water content by increasing TEWL, decreasing the activity of enzymes involved in maturation and

desquamation leading to dry , flaky skin and a decreased barrier function (Harding, 2004). As many people present with drier skin, during these months, it could be fair to say that dry skin could be deemed as a common occurrence at this time of year. The majority of participants recruited were of an elderly status due to the percentage of elderly people that attend the Podiatry Department at the Southern General Hospital. These patients were also in a position to return on a frequent basis for monitoring. The weather conditions during the study resulted in a number of participants cancelling their appointments due to adverse weather conditions, lack of transport or a flare up of medical conditions in relation to the weather. The age of the patients could also have had an effect on the results as the aged skin is generally less elastic and less hydrated, and due to the winter months low humidity and temperature their symptoms can be more severe (Sato et al, 1998). Therefore, in future studies when recruiting patients it would be an advantage to consider the climate of the season and age of patient.

This study originally was to include the use of the Cutometer MP 580 elasticity probe, to investigate whether applying a moisturiser containing urea on a frequent basis improved the skins elasticity. However, during the study it was discovered that the probe utilized was too small to apply the suction method required to the taut skin area around the heel. The type and age of the patient's skin also had an effect; the elasticity probe was effective on participants with less taut skin and a lack of fatty fibro padding in the heel area. However, in general most participants' skin elasticity levels could not be measured with the probe. Unfortunately, the pilot study participants presented with aged, loose skin and therefore elasticity readings were achieved, therefore the problem was not highlighted until later in the study. The cutometer MPA 580 probes can be supplied in a range of sizes and it is suggested for future studies in this area of skin that a larger probe should be purchased.

The acetate-measuring instrument used in this study was robust and allowed the researcher to obtain skin hydration readings from the same area of skin at each visit. Thus ensuring that the results collected were a true reflection of the creams effect on the hydration levels of the skin.

The project demonstrated that both creams were effective in treating anhydrosis, however the results of this project and the post project questionnaire suggests that 69% of people preferred to use the 10% urea cream as was of a nicer consistency, easier to apply and was fully absorbed into the skin. The results are comparable with previous studies where emulsion-containing urea has been characterized by unfavorable aesthetics, which is likely to have an effect on the user's compliance (Savic et al, 2004). Taking into account the external climate factors, participant compliance which cannot be controlled and that the protocol for application of the creams may not have been adhered to, there was still a significant improvement in the patient's skin condition with use of both creams.

Conclusion

The results of this project suggest that a 10% urea cream is more cosmetically acceptable; however, the 25% urea cream may be significantly more effective in treating the actual condition. Therefore as podiatrists, we have a duty to promote to our patients the most efficacious cream in this case the 25% urea cream.

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Key Words

- **Anhydrosis**
- **Urea cream**
- **Hydration**
- **Cutometer MPA 580**
- **Comparative study**

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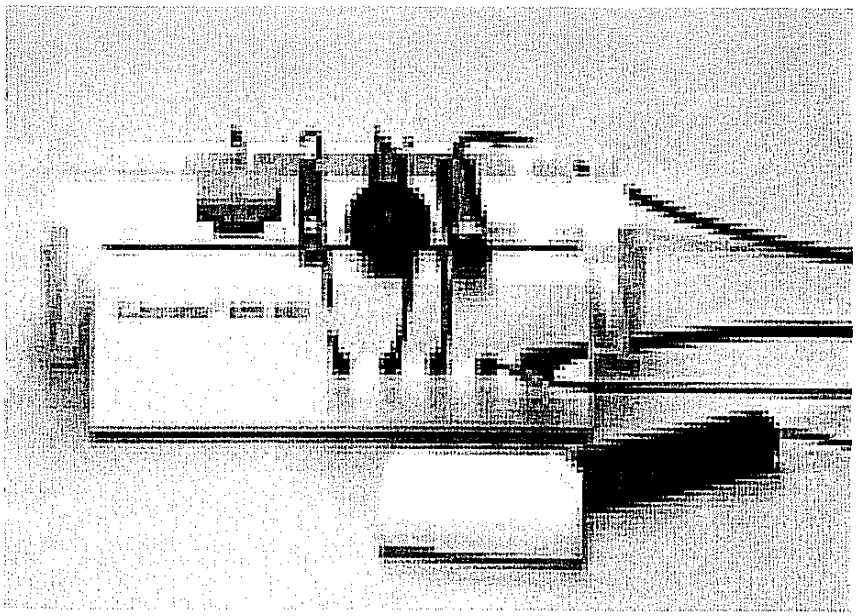
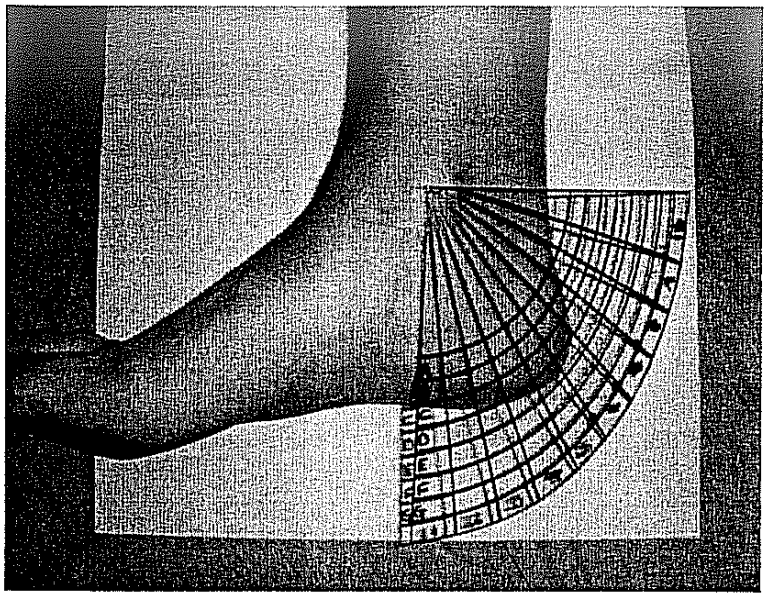
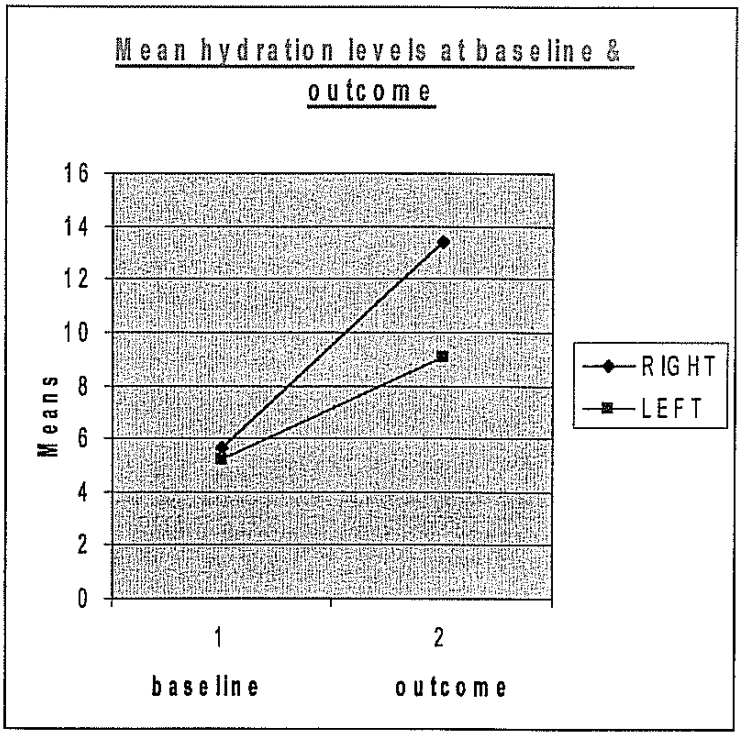
Picture 1: **Cutometer MPA 580 and attached probes.**



Picture 2: **Acetate – measuring instrument**



Graph 1: **Mean Skin hydration levels at baseline and outcome**



Graph 2: Participants perception of the creams