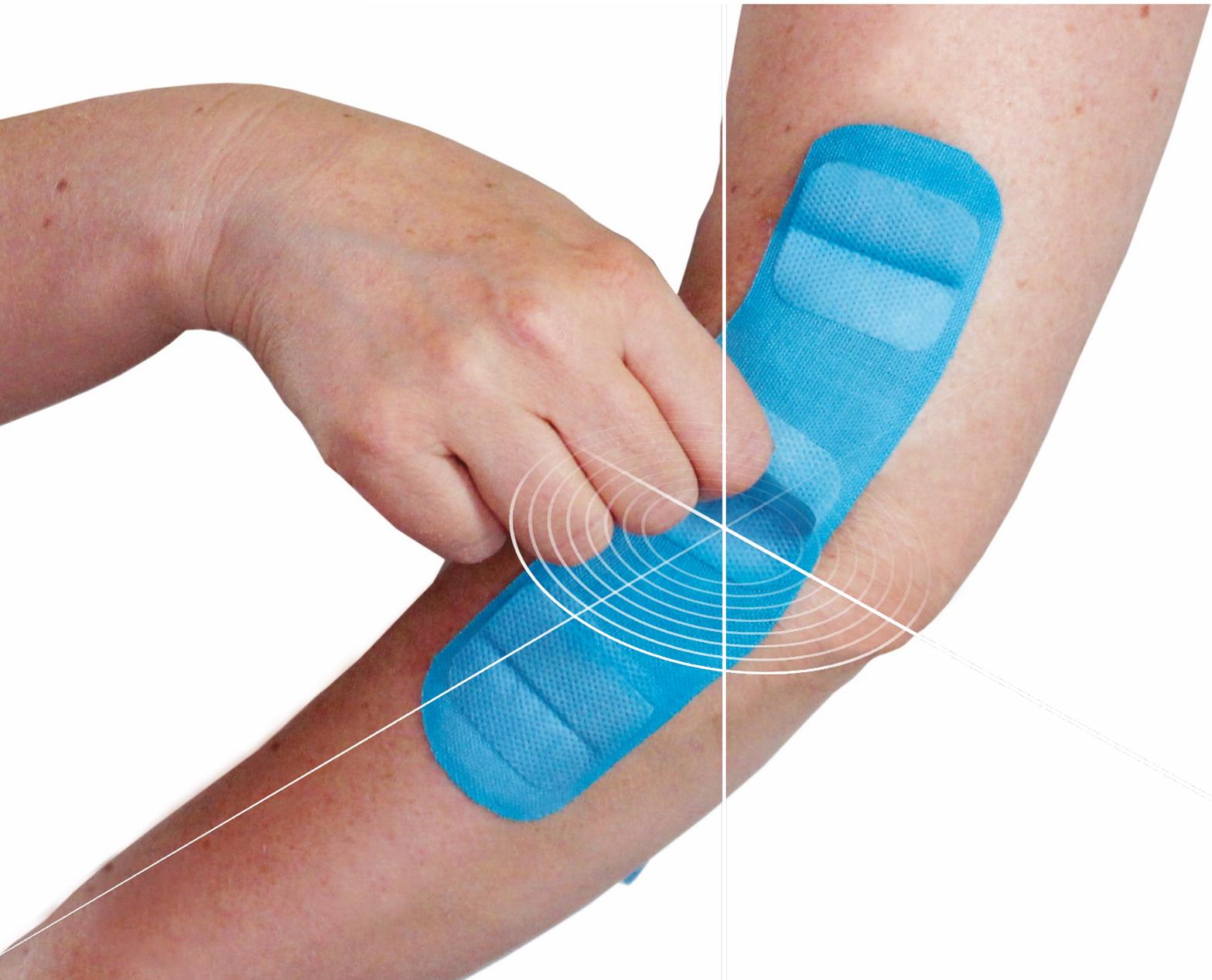


6D TAPE[®]

Six-Dimensional Activation[®]

6D Tape Inc.

6D TAPE FEASIBILITY TEST REPORT



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6D TAPE FEASIBILITY TEST REPORT

Introduction

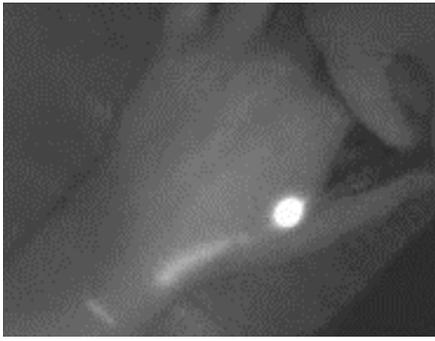
6D Tape Inc. company has developed a 6D Tape for lymphatic drainage taping applications. To date, so-called "classic" tapes have not provided the slightest evidence to support the concept that claims to favor local lymphatic drainage. 6D Tape is distinguished by the presence of sequential perpendicular folds by which one can mobilize the tape and the skin surface once the tape is attached to the skin. The mobilization has 6 degrees of freedom, i.e. acting on both rotations and on the three conventional axes of motion X, Y, and Z. The amplitudes of the movements are important according to the axes considered and are usually between millimeter and centimeter.

6D Tape Inc. asked the coordinator to examine the following feasibility question: *Could 6D Tape have a local influence on the lymphatic drainage of a normal lymphatic network?*

Methodology

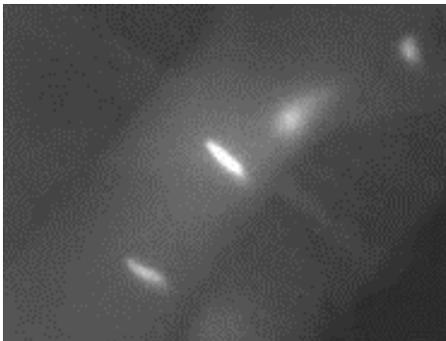
The methodology is based on the use of Near Infrared Fluorescence Lymphatic Imaging (NIRFLI) which provides real time fluorescence pictures of the superficial lymphatics collectors and lymph bolus displacements inside. Number of boluses/time and mean velocity of the bolus displacement can be objectivated. This provides information about an increase or a decrease of lymph traffic in superficial lymphatic collectors and lymphatic draining in the studied anatomical territory. Visualization is achieved using NIRFLI camera which observes the wavelengths of the near infrared light. In addition, a normal camera fixed on the NIRFLI camera provides pictures in human visible light at the same time. Both cameras are confocal.

The experiment is carried out in a room hidden from natural light. An intradermal injection of diluted Indocyanine Green (0.4ml water contain 0.02mg ICG) is performed by the physician. The first injection point is located on the dorsum of the left hand between the 1st and the 2nd metacarpal bone in a healthy volunteer subject as shown in the Photograph 1 a. The second injection is realized at the level of the 5th metacarpal bone.



Photograph 1 a. Intradermal injection of Indocyanine.

The cameras are placed vertically 15 cm up from the area where the 6D Tape is attached to observe both the taped area and the area immediately proximal to the tape. Measurement lines are spaced 50 mm apart in the form of horizontal fluorescent lines on the skin of a healthy subject as shown in the Photograph 1 b.



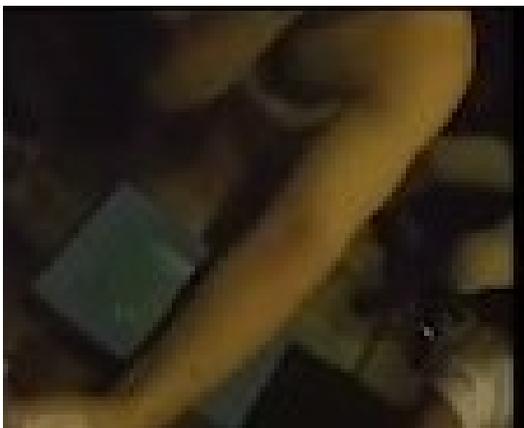
Photograph 1 b. Fluorescent markers on the skin.

Variables observed

The primary variable is the modification of lymph bolus traffic under five different experimental conditions. The five experimental conditions of A, B, C, D and E are explained below. Conditions A, B, and C are used as reference conditions for 6D Tape which is utilized in the conditions D and E.

Condition A, Rest

After injection, a rest period of five minutes is observed in order to reach a "steady state" acting as a basal reference. In this condition the subject is at rest and his upper limb is placed horizontally at the phlebostatic level. This condition determines the baseline and serves as a low reference. The rest condition is shown in the Photograph 2.



Photograph 2. Rest Condition.

Condition B, Voluntary Mobilization

In this condition, the fluids located in the extracellular matrix in the area of the injection site are increased by the muscular activity of the local muscle, i.e. by moving the wrist horizontally from left to right and vice versa. Due to muscular activity the local forces stretch the extracellular matrix and the initial lymphatic veins. This contributes to the transfer of the fluid from interstitium to the lymphatic system. Otherwise the condition is like the Rest Condition A as can be seen from Photograph 3. This condition arbitrarily determines an intermediate line serving as a mean reference when it is desired to test the effect of an external action to the system.



Photograph 3. Condition of voluntary mobilization by normal camera.

Condition C, Manual Lymphatic Drainage (MLD), Fill & Flush Method

In this condition, fluids located in the extracellular matrix in the area of the injection site are forced to penetrate together with Indocyanine into the local initial lymphatic network by applying **manual lymphatic drainage using fill & flush method**. Photograph 4 shows manual lymphatic drainage condition taken by fluoroscopy and normal camera.



Photograph 4. Manual lymphatic drainage condition by fluoroscopy and normal camera.

Condition D, mobilization with a single 6D Tape handle

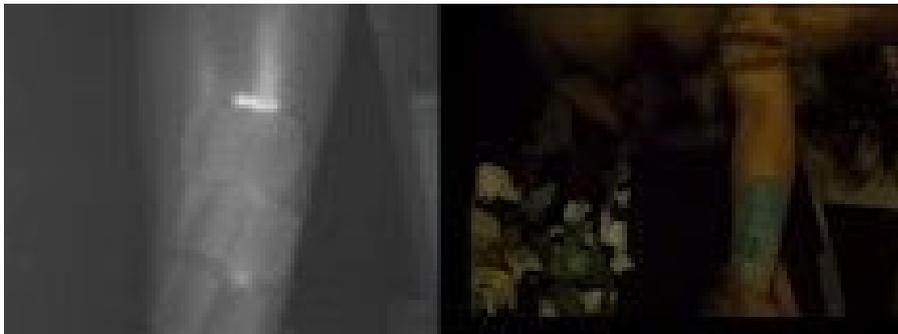
In this condition just one 6D Tape handle strip is pulled up and down (but not pushed), rotated and moved horizontally. The 6D Tape strip that is manipulated is placed over the right side of the hand as shown by an arrow in the Photograph 5. Three different manipulation sequences of D1, D2, and D3 with a single handle strip are performed.



Photograph 5. 6D Tape condition D by fluoroscopy camera and normal camera.

Condition E, 6D Tape handles close together, mobilization with five 6D Tape handles

Under condition E five 6D Tape handle strips are added and located close to each other. The original area between the two markup lines is also left below the 6D Tape strips. The observation area of fluorescence movement is after the second mark-up line. The condition E is shown in the Photograph 6 below.



Photograph 6. 6D Tape condition E by fluoroscopy camera and by normal camera.

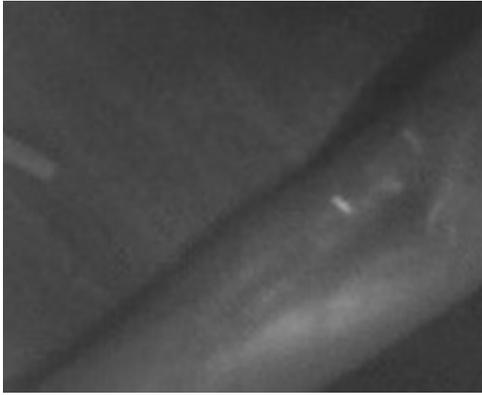
The application method is as follows: a Push or a Fill sequence, i.e. push to fill at the injection point, followed by a Pull or a Flush-type sequence, i.e. mobilization of 6D Tape by pulling from distal to proximal. This condition reminds mobilization sequence of manual lymphatic drainage like "Fill and Flush". The used 6D Tape mobilization techniques are pull, push, rotate, and horizontal move. Three different manipulation sequences of E1, E2, and E3 are performed.

Results

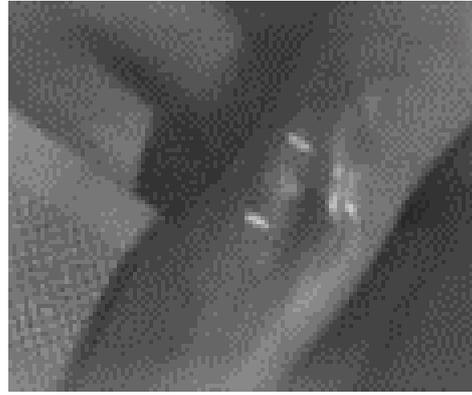
Conditions A, B, C provide current observations and serve as benchmarks for evaluating observations of 6D Tape conditions D and E.

Results in Condition A

In this condition, the production of lymph is very limited. The observation of the move of the lymph within the five minutes observation period showed very limited lymph flow.



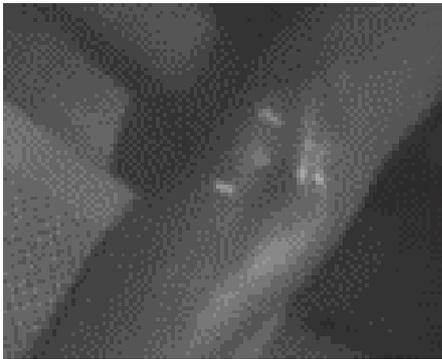
Photograph 7 a. Start of the rest condition.



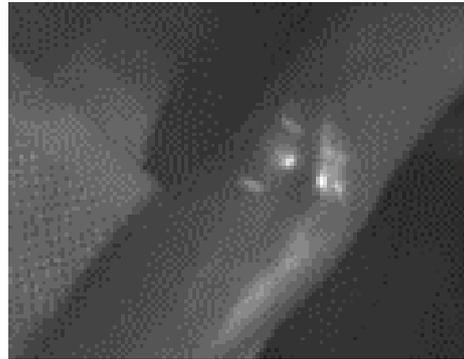
Photograph 7 b. End of the rest condition.

Results in Condition B

The manipulation time was 74 seconds. First small sign of lymph flow was observed 30 seconds after the start of the voluntary mobilization period.



Photograph 8 a. Start of Condition B.



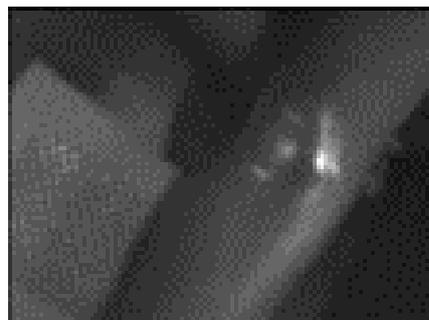
Photograph 8 b. End of Condition B.

Results in Condition C

The manipulation time was 42 seconds. First signs of lymph flow were observed 10 seconds after the start of the manipulation. This condition generates a lymph bolus movement in each maneuver.



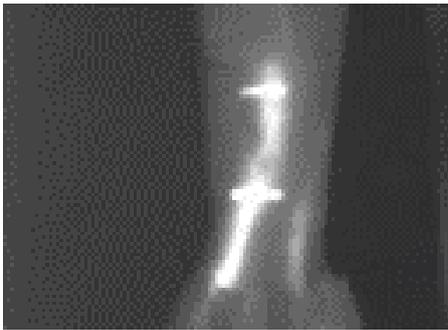
Photograph 9a. Start of Condition C.



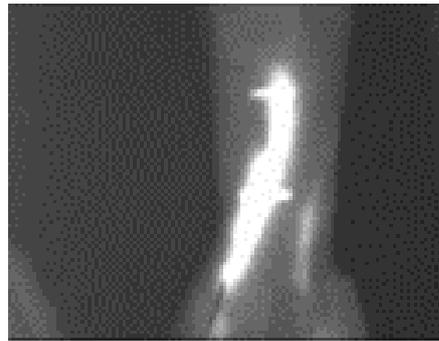
Photograph 9b. End of Condition C.

Results in Condition D

First manipulation sequence D1 was 70 seconds. First visual signs of lymph flow were observed in 10 seconds after the start of this manipulation sequence. After 25 seconds flow of lymph boluses in terms of increased fluorescence was clearly observable in the locating areas as new lymph boluses crossed the benchmark measurement lines. After 25 seconds to 70 seconds the lymph flow continued to increase as manipulation continued. The mobilization of just one 6D Tape handle had influence on the transfer of fluids from the interstitial space to the lymphatic system and on the progress of the lymph in lymphatic collectors. The start and end situations can be seen in the Photographs 10 a and 10 b.

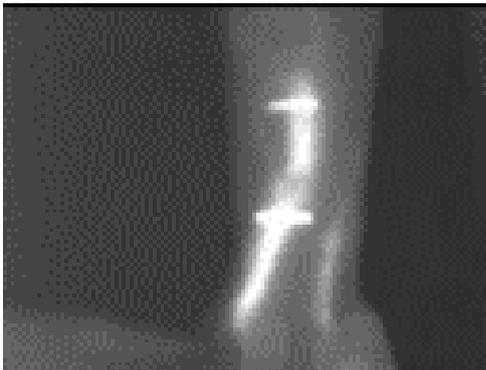


Photograph 10 a. Start of Condition D1.

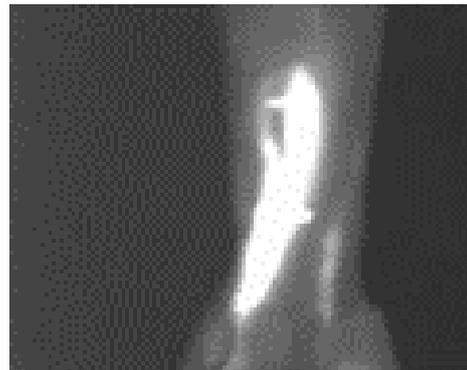


Photograph 10 b. End of Condition D1.

The second manipulation sequence D2 was 187 seconds. Results confirmed the findings from the first manipulation. The start and end situations can be seen in the Photographs 10 c and 10 d.



Photograph 10 c. Start of Condition D2.



Photograph 10 d. End of Condition D2.

The third manipulation sequence D3 was 148 seconds. Results confirmed the findings from the first manipulation. The start and end situations can be seen in the Photographs 10 e and 10 f.



Photograph 10 e. Start of Condition D3.

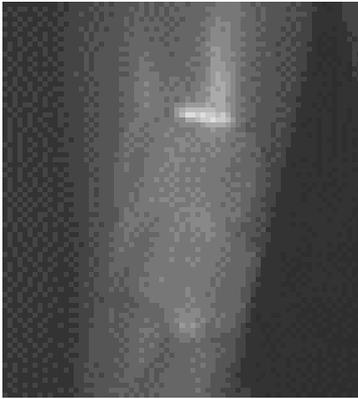


Photograph 10 f. End of Condition D3.

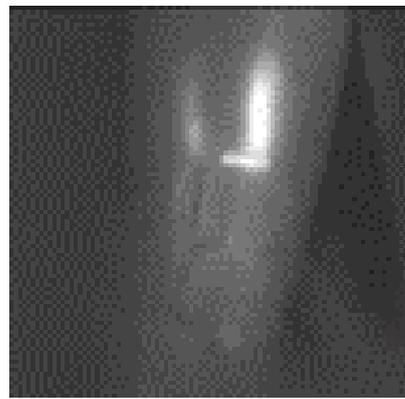
In the beginning of all the sequences D1, D2, and D3 the increase of fluorescence became slowly visible but towards the end of manipulation cycle the amount of fluorescence continued steadily to increase in the area of observation and in between the measurement lines.

Results in Condition E

First manipulation sequence E1 lasted 29 seconds and clear signs of increased lymph flow were observed behind the second marker line. The start and end situations are shown in the Photographs 11 a and 11 b.

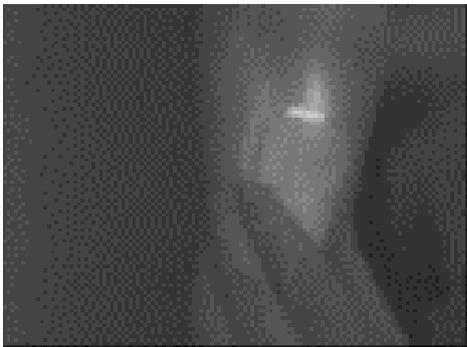


Photograph 11 a. Start of Condition E1.

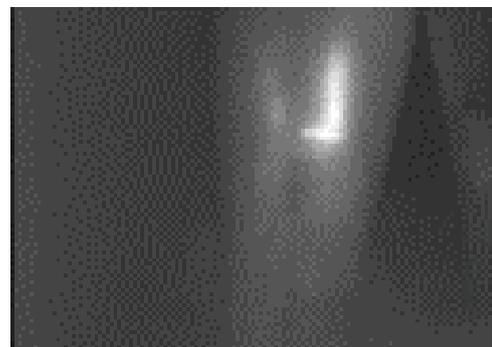


Photograph 11 b. End of Condition E1.

The second manipulation sequence E2 lasted 47 seconds and clear signs of increased lymph flow were observed again behind the second marker line. The start and the end situations are shown in the Photographs 11 c and 11 d.

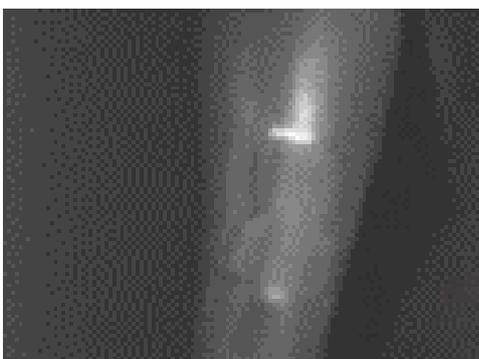


Photograph 11 c. Start of Condition E2.



Photograph 11 d. End of Condition E2.

The third manipulation sequence E3 lasted 32 seconds and confirmed the findings of the first and the second manipulation sequences. The start and end situations are shown in the Photographs 11 e and 11 f.



Photograph 11 e. Start of Condition E3.



Photograph 11 f. End of Condition E3.

The increase of fluorescence was rapid and highest in the end of each manipulation cycle of E1, E2, and E3 when the 6D Tape handle that was nearest to the marker line was manipulated.

Discussion

The results of experimental conditions of A, B, C, D and E are discussed and compared in this Section. Conditions A, B, and C are used as reference conditions for conditions D and E where 6D Tape was utilized. The primary variable is the modification of lymph bolus traffic under five different experimental conditions of A, B, C, D and E. The results are compared in Table 1 according to the following variables: presence of lymph bolus traffic, increase of lymph bolus traffic, sequence length, and manipulation technique.

| Variable/Condition | Rest | Muscle Mobilization | MLD, Fill&Flush | 6D Tape / One Handle Strip | | | 6D Tape /Five One Handle Strips | | |
|---------------------------------|--------------|---------------------|----------------------------|-------------------------------|--------------------|--------------------|-------------------------------------|------------------------------|------------------------------|
| | A | B | C | D 1 | D 2 | D 3 | E 1 | E 2 | E 3 |
| Presence of Lymph Bolus Traffic | Very limited | Small sign | Clear sign | Clear sign | Clear sign | Clear Sign | Clear sign | Clear sign | Clear Sign |
| Increase of Lymph Bolus Traffic | No | Very limited | Pulse in each manipulation | Low but continuous | Low but continuous | Low but continuous | Continuous, rapid in the end | Continuous, rapid in the end | Continuous, rapid in the end |
| Sequence Length [s] | 300 sec | 74 sec | 42 sec | 70 sec | 187 sec | 148 sec | 29 sec | 47 sec | 32 sec |
| Manipulation Technique | Rest | Wrist Movement | Fill & Flush | Pull, Rotate, Horizontal Move | | | Pull, Push, Rotate, Horizontal Move | | |

Table 1. Results of the experimental conditions of A, B, C, D, and E.

In Condition A the subject is at rest and presence of lymph flow is very limited, and no increase of lymph bolus traffic is detected as can be seen from Photographs 7 a and 7 b. The lymph flow and its frequency are proportional to the fluid excess located in the extracellular matrix of injected region. This excess fluid is determined by the filtration of the local microcirculation.

In Condition B active mobilization of tissues by the muscles around the injection site promotes the fluid production to be drained and penetration of ICG into the local initial lymphatic network. The lymph boluses progress into the lymphatic collectors which are dependent of the injection region only by the autonomous contraction of the lymphangions. Condition B generates faster lymph production, as observed by a slight increase of the lymph bolus passage frequency, than during the rest Condition A but increase of lymph flow is still very limited as can be seen from Photographs 8 a and 8 b.

In Condition C the interstitial fluid is pushed manually into the initial lymphatic and then into the lymphatic collectors tributary from the injection region. The lymph traffic, or lymph bolus passes, correspond to each manipulation performed as a clear sign of fluorescence move is visually observed. In other words, the signs of lymph flow are directly linked to manipulation pulses, and the signs of lymph flow are more numerous than under condition B.

In Condition D the mobilization of just one 6D Tape handle strip is performed by pulling it up and down (but not pushing), rotating and horizontally moving. This mobilization had continuous influence on the transfer of the fluids from the interstitial space to the lymphatic system, and on the progress of the lymph in lymphatic collectors. The difference between Condition C and D was that in the Condition D the amount of fluorescence in the area of observation was continuously increasing. The difference in the end of manipulation of Conditions C and D1 can be seen from the Photographs 9 b and 10 b respectively. In other words, the amount of fluorescence continuously increased in the

observed area in Condition D1 as fluorescence started to fill the area between the marking lines. Condition D1 was repeated in Conditions D2 and D3 which systematically verified the reproducibility of the phenomenon as can be seen from Photographs 9 c & 9 d and Photographs 9 e & 9 f.

In Condition E five 6D Tape handle strips are located close to each other as shown in the Photographs 11 a – 11 f. The original area between the two markup lines is under the 6D Tape strips, and the observation area of fluorescence movement is now after the second mark-up line. The application is different to Condition D as in Condition E also pushing is used when pumping up and down with the 6D Tape handles. The second difference is that in Condition D only a one handle strip was utilized.

In the beginning of the all manipulation sequences E1, E2, and E3 the increase of fluorescence flow became visible slowly but in the end of the manipulation cycle the speed of visible fluorescence flow increased very much when the handles near the marker line were manipulated. An explanation for this rapid flow increase in the end of the cycle is as follows. Firstly, the manipulation of the distally located handles started to generate lymph flow with fluorescence into the area of the proximal handles Secondly, the manipulation of the most proximal handles gave more speed to the underlying lymph - within 6 seconds a rapid increase of lymph flow was observed. This phenomenon happened systematically in all the three sequences of E1, E2, and E3. Consequently, the reproducibility of this phenomenon was confirmed.

Conclusions

The question asked in the beginning of the feasibility test was as follows: *“Could 6D Tape have a local influence on the lymphatic drainage of a normal lymphatic network?”*

In this test it was examined by the method of Near Infrared Fluorescence Lymphatic Imaging (NIRFLI) of the superficial lymphatic collectors that 6D Tape had observable efficiency in increasing the lymphatic drainage of a healthy subject. Consequently, it can be concluded that mobilization of both one 6D Tape handle strip (Condition D) and five 6D Tape handle strips (Condition E) have a local influence on the lymphatic drainage.

In the case of only one 6D Tape handle strip, the manipulation consisted the following maneuvers: pull up and down (but not push down) with simultaneous rotation and horizontal moves. The result was that the increase of lymph flow was low but continuous in the observed area.

In the case of five 6D Tape handle strips, manipulation consisted the following maneuvers: pull up and push down with simultaneous rotation and horizontal moves. The result was that the increase of lymph flow was continuous and very rapid increase was observed when proximal handles near the marker line were manipulated. Based on Conditions D and E it is concluded that it is advantageous or best to apply multiple 6D Tape handle strips that are relatively close together and which are consecutively both pulled up and pushed down with simultaneous rotation and horizontal moves.

When testing with five 6D Tape handles (Condition E) it was found that a functional sequence is to perform at least five manipulations with the handles at the injection site (artificial edema) followed by at least three manipulations with each of the handles in the proximal side.

It is an indisputable conclusion that mobilization of 6D Tape handles makes it possible to mobilize the fluids of the interstitial space towards the initial lymphatic system, and to promote the transport of the lymph within the superficial lymphatic collectors.