A (not so) brief conversation concerning HemaClear™ pressure

Orthopedic Surgeon:

OK, I am convinced that the HemaClear™ works well, but please tell me about the pressure in the limb beneath the ring - I am concern about compression injury.

HemaClear™ Technical Expert:

The pressure inside the limb near the artery is 150-210 mm Hg, depending on the specific model (color). The pressure on the skin just under the ring is between 160 and 410 mm Hg with the highest value for the HemaClear™/60 (leg) brown color. These pressures are within the range accepted as safe for duration of up to 2 hours.

OS:

How did you measure the pressures?

HCTE:

We conducted physiological and clinical studies. We also carried out a computerized mathematical analysis of the pressures developing in the limb with the HemaClear™ in comparison with a standard pneumatic tourniquet.

OS:

Tell me more about the studies.

HCTE:

In the first study we placed the HemaClear™ on the limbs or on pipes of different circumferences and measured the pressure at the surface just under the ring.

OS:

How is it possible to measure these pressures?

HCTE:

We placed a thin soft wall channel under the HemaClear™ ring (between the skin or the pipe surface and the ring) (see **Diagram 1**) and increased the pressure in one end of the channel, until gas started flowing under the ring. This is the pressure that the ring applies to the surface. We repeated this measurement for all the HemaClear™ models and circumference ranges. Here is the diagram that shows the experimental procedure:

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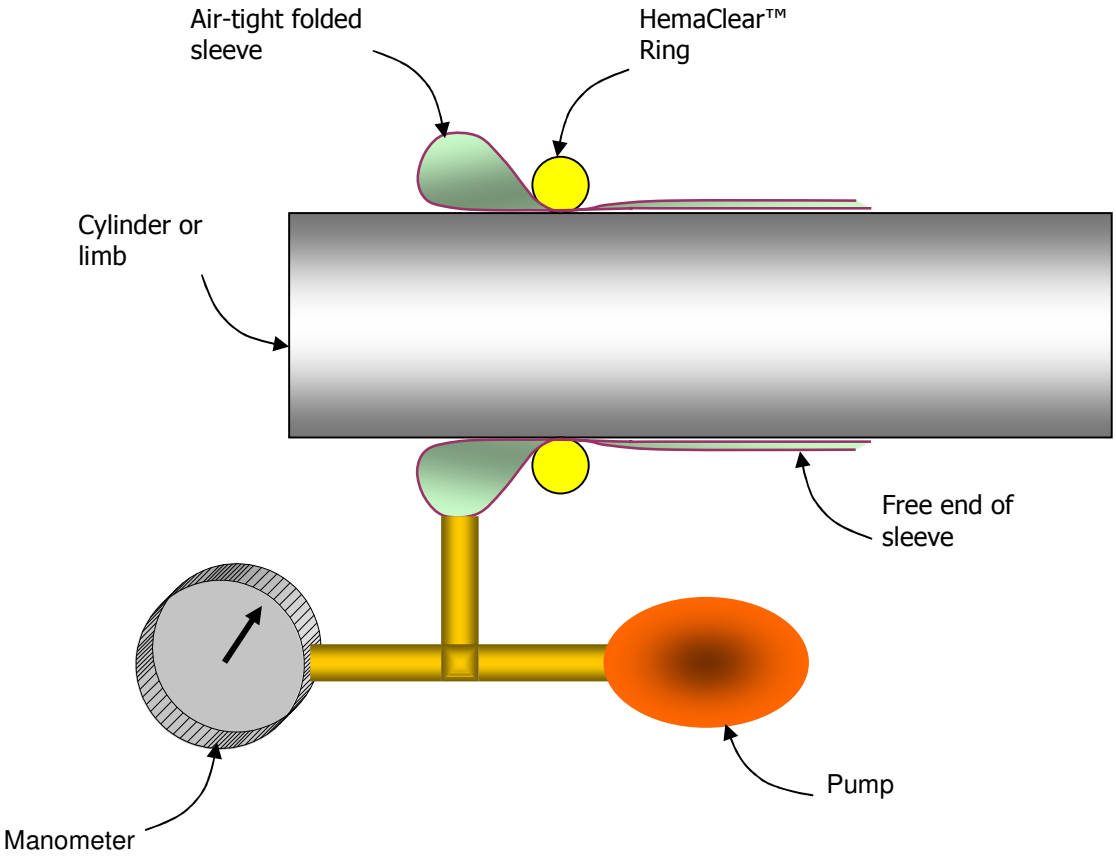

Diagram 1: A schematic diagram of the surface pressure study. A thin wall channel was constructed from an airtight plastic sleeve that was folded onto itself. A connector was inserted into the channel material at its blind end where the pump and manometer assembly could be connected. The HemaClear™ ring was then rolled over the double layered sleeve. The pump increased the flow gradually until air started escaping under the ring and the pressure stopped rising. This pressure is equal to the occluding pressure that the ring applies to the surface.

OS:

Well, this is an interesting way of measuring the pressure that the HemaClear™ ring applies to the skin, but what about the pressure inside the limb?

HCTE:

This was determined by a physiological study with volunteers. We applied the HemaClear™ to their leg or arm and measured their blood pressure while determining if the blood flow was stopped or not. To do so we used a Doppler flow probe. We then asked the subject to isometrically tense all his/her muscles, except the muscles of the limb with the HemaClear™. This maneuver always raises the systolic (and diastolic) blood pressure quite a bit. While the muscles were contracted, we re-measured the blood

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pressure and again searched for flow into the limb with the Doppler probe. This step was repeated a couple of times at different muscle contraction levels. We could then determine the occluding pressure that the HemaClear™ induced at the arterial wall. We repeated the study in subjects of different body build, thin, medium and heavy, with limb circumferences within the range specified for the HemaClear™ models. These data, example of which is shown in Diagram 2, were used to calibrate the HemaClear™ construction.

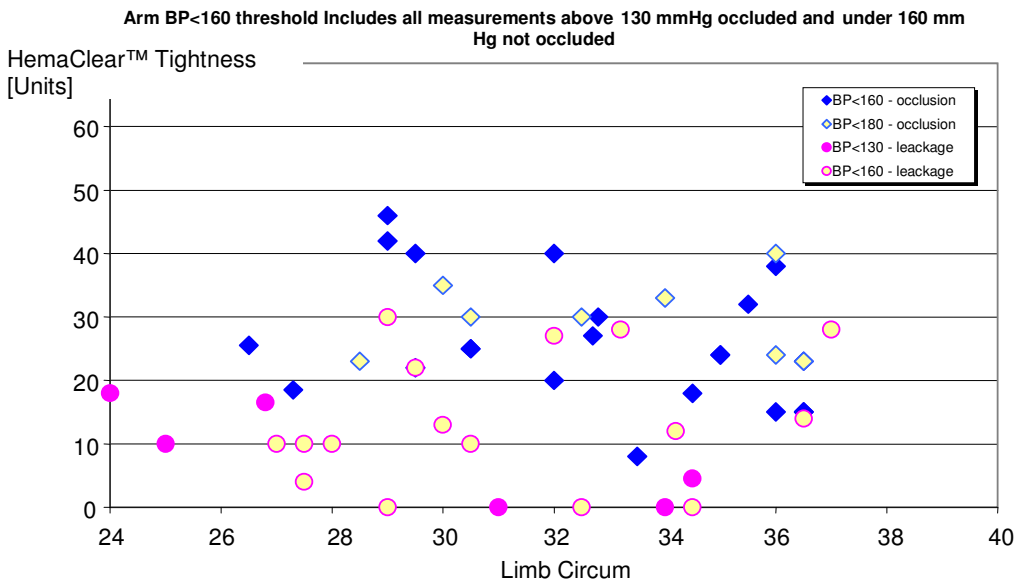

Diagram 2: The x-axis is the limb circumference, the Y-axis is the HemaClear™ tightness (= model). The circles represent runs where the artery was not occluded by a HemaClear™ applied to the upper arm while the systolic blood pressure was less than 160 mm Hg. The squares are from runs where there was no blood flow into the limb despite elevated blood pressure (>130 mm Hg, but less than 160 mm Hg). This part of the study was done in subjects with limb circumferences ranging from 24 to 38 cm. It is easy to see that with HemaClear™ tightness greater than 30, the artery was occluded for all blood pressures between 130 and 160 mm Hg. This level of tightness was chosen for the "red" arm model.

OS:

So you used the blood pressure and the detection of blood flow to measure, non-invasively, the occluding pressure inside the limb. This is a good method, but there is something in this graph that I wouldn't have expected: The threshold between the circles and the squares is independent of the limb circumference! How can it be that the occluding pressure inside a skinny limb and a fat one are the same? My high school physics tells me that the more you stretch an elastic ring, the higher the force it generates….?

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HCTE:

You are absolutely right, the FORCE that the ring generates is higher when it is applied on a wider limb, but you must remember that PRESSURE is the FORCE divided by the AREA, and in a wider limb, the contact AREA under the ring is also larger. Therefore, the ratio of the FORCE to contact AREA which is the PRESSURE remains essentially the same.

OS:

Ahah, the force is greater, but the pressure remains the same. Now this is smart! Does this mean that I can place the HemaClear™ anywhere I want on the limb and it will work?

HCTE:

As long as it is within the ranges specified by OHK (the manufacturer), 24-40 cm for the HemaClear™/40 and 30-60 cm for the HemaClear™/60. If you use it on a narrower limb it is under the occluding threshold and will not work. If you use it on a fatter limb, you stretch the ring beyond the linear elastic properties of the silicone and you may create pressures that are higher than the safe upper level.

OS:

OK, I'll pay attention to this. Is there a model for very obese patients? We see more of them as they get older and wear their knees more than non-obese patients.

HCTE:

Yes, we have a HemaClear™/90 model for patients with a limb circumference of 50-90 cm. You should also know that you can use the HemaClear™ /60 (the larger size) on an arm when the circumference is greater than 40 cm (heavy metal athletes…), and more importantly, you can use the HemaClear™/40 yellow model on the lower limb on parts of the leg that are less than 40 cm in circumference (below the calf muscle in the majority of patients). Since the HemaClear™ is sterile, you can place it 15 cm above the ankle for all ankle and foot procedures (unlike the non-sterile pneumatic cuff) and at this level you can use the HemaClear™/40 yellow model in the vast majority of patients.

OS:

These are good points. Now, tell me about your mathematical models. Not that I understand much in engineering or math, but being that you mentioned it….

HCTE:

These models are very powerful because they can predict the pressure distribution in every point inside the tissue. Not only that, but they can also

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tell us the deformation or change in shape that the tissue undergoes. Here are a couple of pictures that show what happens.

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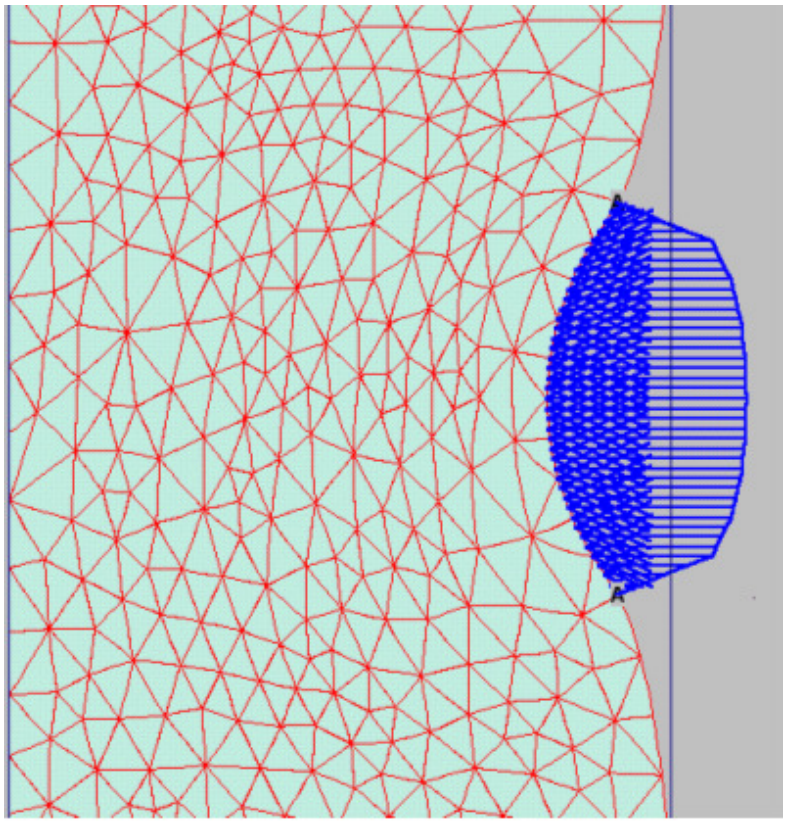
Diagram 3a:

This figure shows the way the computerized model works. The volume of the model (ring in dark blue and limb in light blue here) is divided into a grid of elements indicated by the lines and nodes. The computer then solves the equations of force and displacement for each element, taking into account the neighbors. The next two figures show results from this model. Note: the figure shows only half of the limb (cut lengthwise) the other half is symmetric.



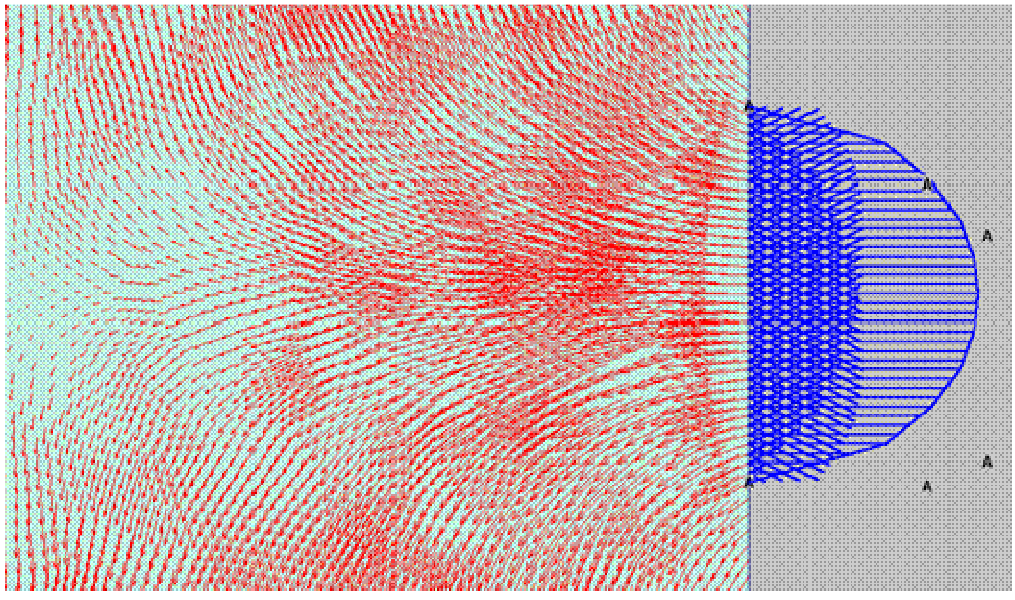


Diagram 3b: This figure shows the displacement field inside the limb under the ring loading. The little red arrows indicate the direction and extent of motion of the tissue elements once the load is applied

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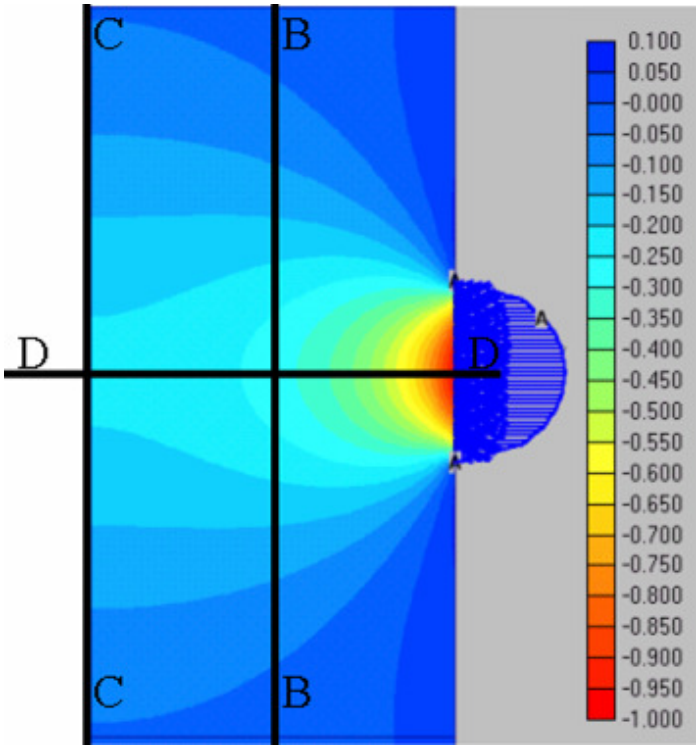
Diagram 3c:
The pressure distribution inside the “limb” caused by the ring load. The color scale indicates the fraction of the skin pressure that develops inside the tissue.



OS:

I am not sure I understand it all, but the pictures are certainly nice. Now I have this problem: we have been taught for many years that occluding the blood flow into the limb using a wide cuff requires less pressure than with a narrow cuff. The HemaClear™ is even narrower than our narrow pneumatic cuff and it works. Can you explain this to me?

HCTE:

Let us first consider a blood pressure cuff. The whole method of measuring blood pressure is based on the notion that, when using an appropriate cuff size, the pressure in the cuff and the pressure somewhere inside the limb just outside of the artery are exactly the same. Thus, when the patient's systolic pressure is 120 mm Hg and the cuff pressure is 119 mm Hg the tissue pressure around the artery will also be 119 mm Hg and the artery will open up just enough at the peak of each systole to permit a small amount of blood to escape downstream under the cuff and generate the Korotkoff sound. The pressure inside the limb is not uniform as shown in the figure below.

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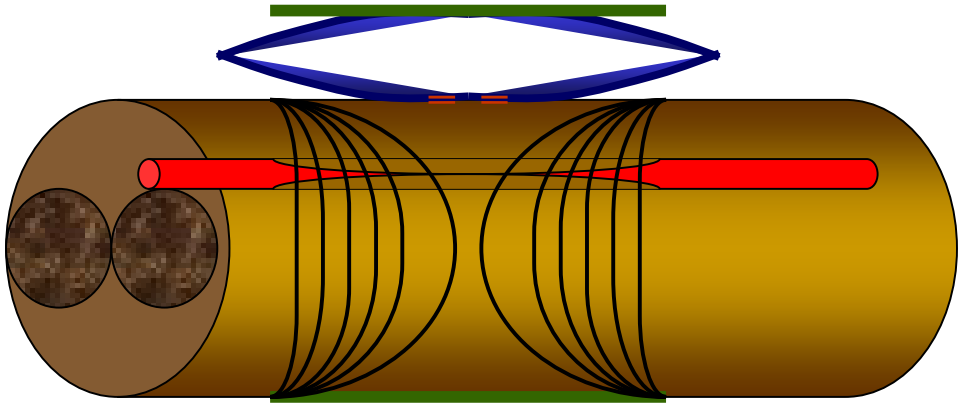

Diagram 4: A schematic drawing of a limb (forearm) with a pneumatic cuff around it and a compressed artery (in red). The curved lines indicate equal pressure regions (isobars) inside the limb. The chart below the drawing is the pressure inside the limb along its axis. Clearly, the pressure in the limb at the middle of the cuff is the same as in the cuff itself, but outside of the mid-region the pressure drops quickly down to zero at the two ends of the cuffed limb.

When a pneumatic tourniquet is inflated the same thing happens as when we measure blood pressure. We may need, however, to elevate the tourniquet pressure if it is narrow, because there is no region at all where the tissue pressure is the same as the cuff pressure. The narrower the cuff, the higher the skin pressure we need to apply. This is why narrow tourniquets need higher pressures than wide ones to occlude the artery.

OS:

OK, now what about the HemaClear™?

HCTE:

The HemaClear™ is not different from a narrow cuff, in a sense that it requires a higher skin pressure to achieve sufficient tissue pressure to occlude the artery. As a matter of fact, we found that the skin pressure is 120 to 180 mm Hg higher than the mid tissue pressure.

OS:

This means that the HemaClear™ skin pressure is in the same range as with the narrow pneumatic cuff?

HCTE:

Yes, indeed, and both are somewhat higher than with the wide cuff, but this is at the skin level. Inside the limb the pressures fall (as shown in **Diagram 3C**) and only a small part of the limb is compressed (even smaller than with narrow or wide cuffs) and the internal pressures are just enough to occlude the artery!

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OS:

This is good. Can you tell me some more about the mechanical differences between the HemaClear™ and the pneumatic cuff?

HCTE:

In our work on the HemaClear™ we came across data that indicate that the HemaClear™ may actually be safer than the wide cuff with respect to its effect on nerves.

OS:

How can that be?

HCTE:

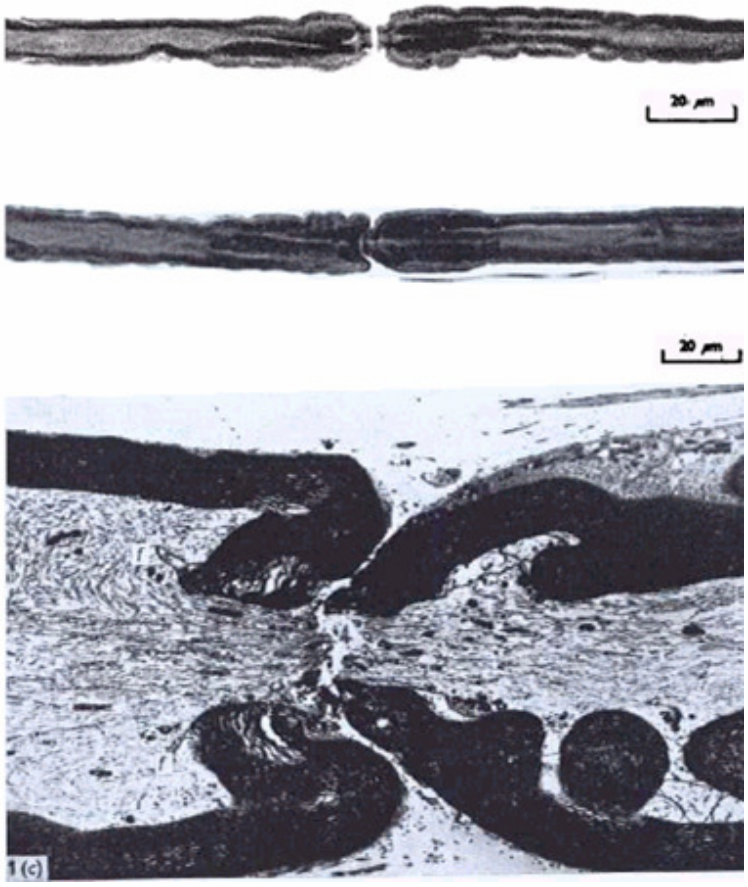
There is an important study published in the Journal of Anatomy in 1972 by Ochoa, Fowler and Giliatt from the Institute of Neurology, Queen Square, London, (113, 433-455). The title of the article is "Anatomical changes in peripheral nerves compressed by pneumatic tourniquet". In that study the authors showed that when pressure is applied over a length of a nerve with a wide pneumatic cuff the nerve has a tendency to elongate and its sections just proximal and just distal to the cuff region telescope ("invaginate") into the free sections of the nerve (not beneath the cuff). Bellow are histological pictures from this paper.
Ochoa et al. found that the telescoping phenomenon, and the subsequent

Diagram 5:

<u>Top:</u>
Normal node of Ranvier.

<u>Middle:</u>
Anormal node of Ranvier, with minimal invagination from left to right.

<u>Bottom:</u>
Electron Microscope picture showing the details of the invagination.



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de-myelination and damage to the nerves were essentially limited to the edges of the cuff as shown in the next two figures. The figures show the location of damage with respect to the cuff position, from a single example and as a histogram from over 800 dissected nerve fibers.

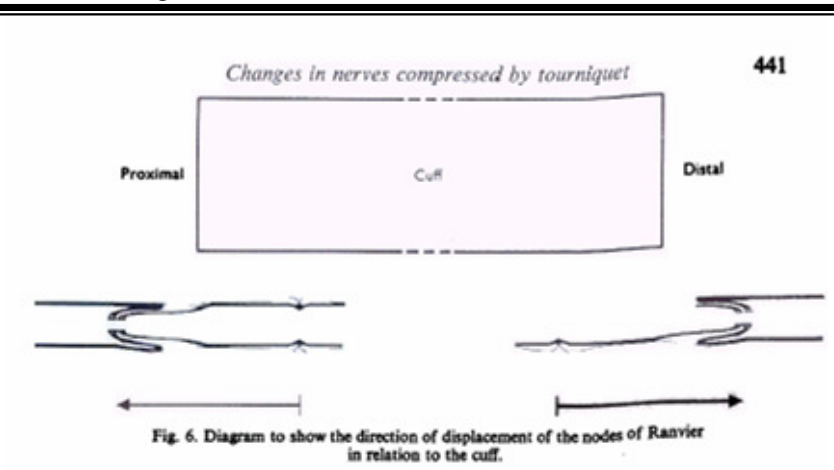

Fig. 6. Diagram to show the direction of displacement of the nodes of Ranvier in relation to the cuff.

Diagram 6: Showing the direction of displacement of the nodes of Ranvier in relations to the cuff.

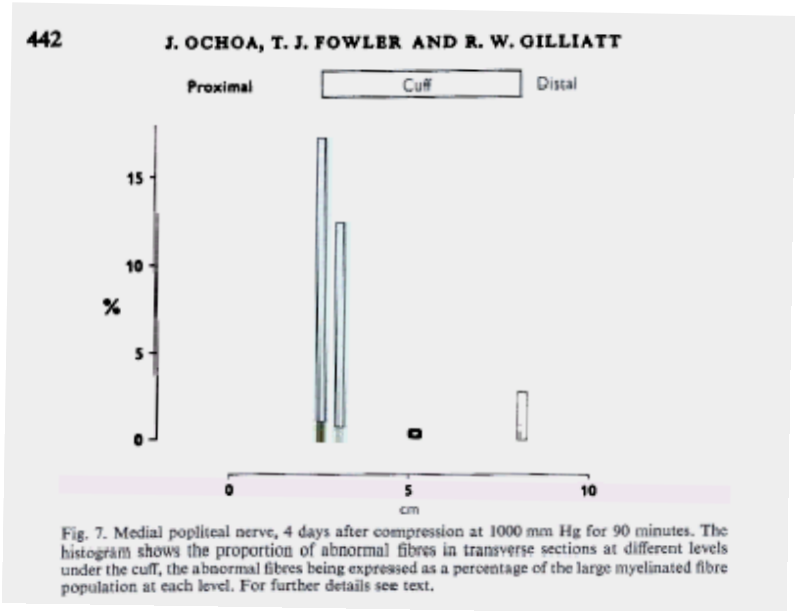

Fig. 7. Medial popliteal nerve, 4 days after compression at 1000 mm Hg for 90 minutes. The histogram shows the proportion of abnormal fibres in transverse sections at different levels under the cuff, the abnormal fibres being expressed as a percentage of the large myelinated fibre population at each level. For further details see text.

Diagram 7: A histogram showing the proportion (in %) of abnormal fibers at different levels under the cuff. Note the concentration of abnormal fibers at the two margins, while there are virtually none in the middle (where the pressure is the highest).

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OS:

Will it be correct to conclude that it is not the actual pressure that caused the damage, but the pressure GRADIENT at the edges?

HCTE:

Yes. This is correct, but it is best summarized by the Authors own words who wrote in their discussion:

> *"Why are the lesions concentrated under the edges of the cuff? This could be explained by the pressure gradient in the tissues between the parts under the cuff and those beyond its edge. With the relatively wide cuff we have used, the gradient would be maximal under the edges of the cuff and least under its center. Without such a gradient, one would not expect axoplasmic movement or displacement of the nodes of Ranvier to occur, even if the absolute pressures in the tissues are high. As an example of the ability of a peripheral nerve to withstand high pressures provided that there is no gradient between one part and another, one may cite the experiments of Grundfest (1936), who showed that when an isolated portion of frog nerve was wholly enclosed in an oxygenated pressure chamber, pressures of the order of 1000 atmospheres were necessary to abolish conduction. It is interesting that both Edwards & Cattell (1928) and Bentley & Schlapp (1943) considered that the effect of pressure on peripheral nerves was to produce distortion which was maximal at the edges of the compressed part. The latter authors found that when exposed cat sciatic nerve was compressed between two pneumatic cushions, most of the fibers appeared to be blocked at one or other edge of the compressed zone, rather than at the center."*

OS:

This is fascinating. So, if I understand correctly, with the HemaClear™'s pressure being applied over a very short segment of the nerve, there is no elongation and therefore reduced risk to nerve telescoping and subsequent paralysis.

HCTE:

Yes, this is what we also think.

OS:

Any additional support to show the reduced risk of nerve damage?

HCTE:

We actually saw the elongation effect in our finite element model even before we came across Ochoa's study. You may recall the direction and size of the arrows on the left hand side of Diagram 3b. These arrows represent the model predictions of the displacement of tissue elements in the middle of the limb. They all point either up or down, with none under

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the middle of the cuff. Here are a couple of additional figures from the computer showing this effect more clearly:

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Diagram 8:

Displacements at different depths in the tissue. C is in the middle of the limb. Arrow size = displacement.

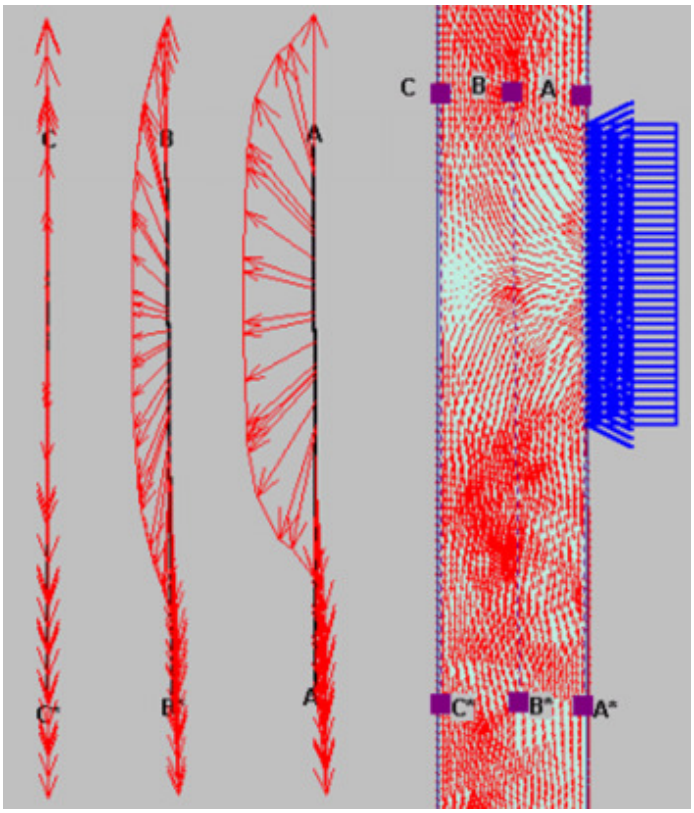
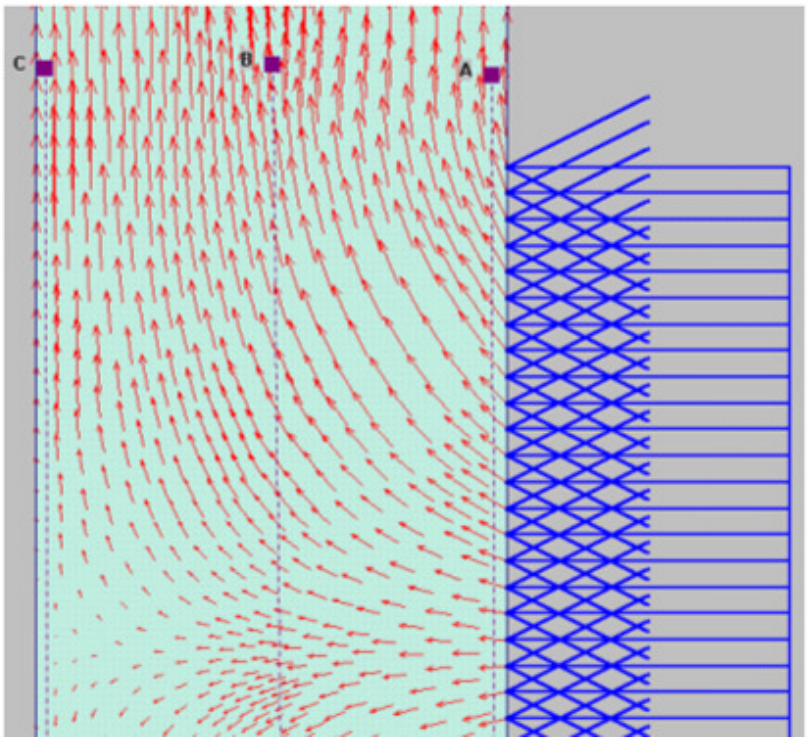


Diagram 9:

Magnified view of the model output showing the displacement magnitude and direction under the cuff. Shown is about a quarter of the full picture, i.e. one side of the limb and slightly more than the upper half of the cuff region. Note that there are no arrows under the middle of the cuff at the center of the limb (line c) and that the lines get longer towards the edge of the cuff.



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OS:

This is fine. All this basic research is very important, and I think I now understand the pressure issue much better, but what is the clinical experience with the HemaClear™? Did you have any reports of compression injury, decubitus soars, damage to tissues (blood vessels, nerves)?

HCTE:

None whatsoever! After several thousands of procedures performed with the HemaClear™ some with up to 2 hours, we have no reports of any complications or side effects.

OS:

With the pneumatic cuff we often see skin bruises or petechiae under the cuff at the end of operation. Is there a similar problem with the HemaClear™?

HCTE:

Not at all. The rolling up of the HemaClear™ and its concentric structure prevent crimping of the skin and we do not see skin damage. Occasionally there is a faint mark on the skin which disappears in a matter of hours.

OS:

One last question, with pneumatic cuff there is a concern that the pressure may change during the procedure or that there will be a variability of applied pressure among patients. Is this a problem with the HemaClear™.

HCTE:

No. OHK, the manufacturer tests each silicon ring for its elasticity as part of the quality control and the tolerance is very tight.

OS:

Thank you for sharing this information with me.

HCTE:

Thank you for the opportunity to discuss these issues with you. We feel that an informed physician is an asset for us. If you have any additional technical questions, please submit them to info@HemaClear.com . Also, please visit our web site at www.HemaClear.com.

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