Flexible Socket with Volume and an Interactive Residual limb Control System

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Introduction

- First phase - Socket design.
- Second phase – Flexible Socket
- **Third phase – Volume management**
- **Fourth phase - Interactive Socket**

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First phase - Socket design.

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Socket design

The Socket Design is a mixture of:

- NSNA - Normal Shape Normal Alignment of Ivan Long.
- CAD-CAM - Contoured Adducted Trochanteric – Controlled Alignment Method, John Sabolich and Tom Guth.
- UCLA CAT-CAM – Christopher Hoyt.
- MAS Marlo Anatomical Socket.
- The New method.

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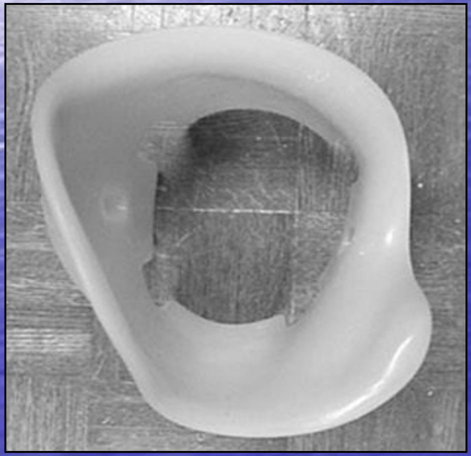
Motis 1947

Long

Breakey

Variations of Ischial Containment Socket Shapes



IPOS

UCLA - Hoyt

Sabolich

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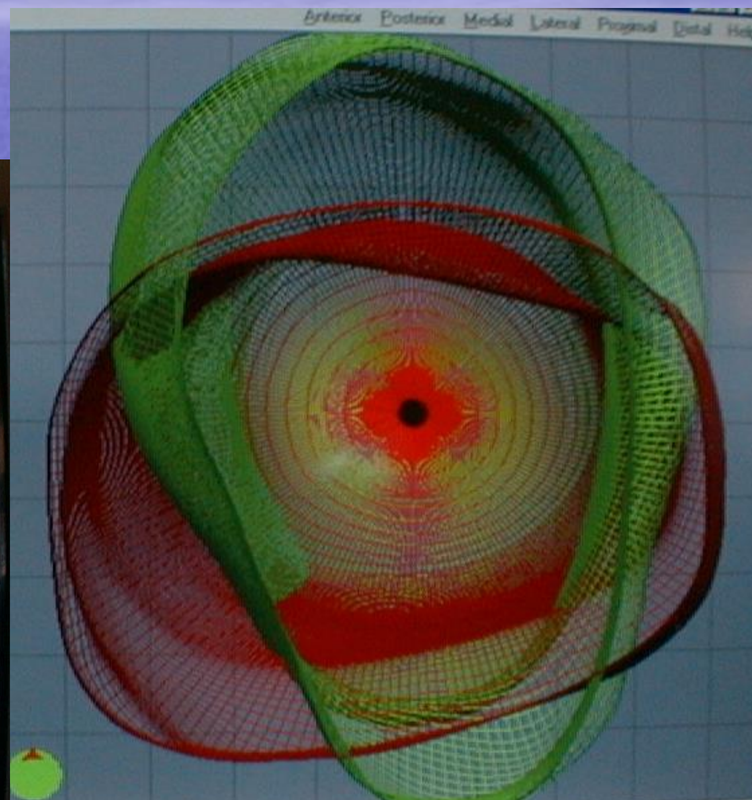
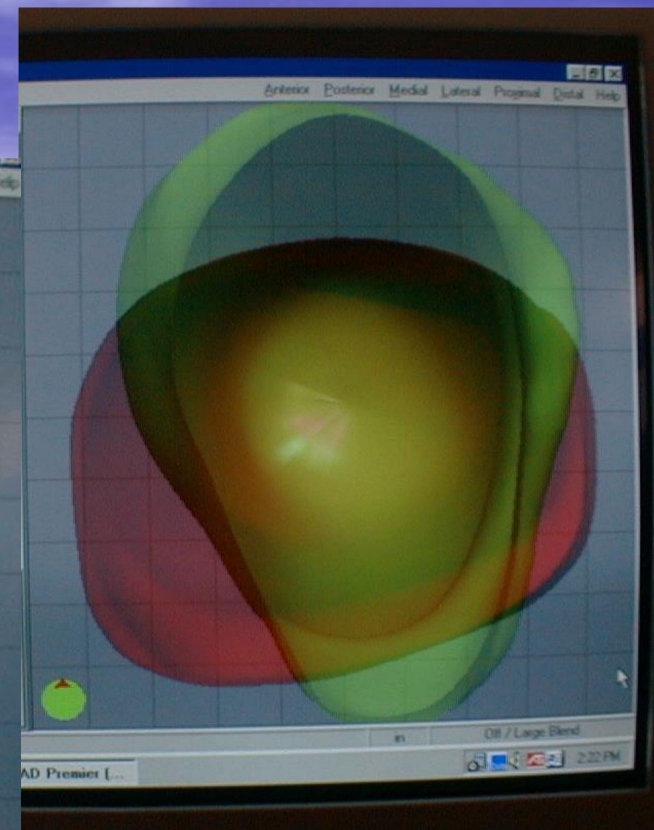
Transfemoral CAT - CAM





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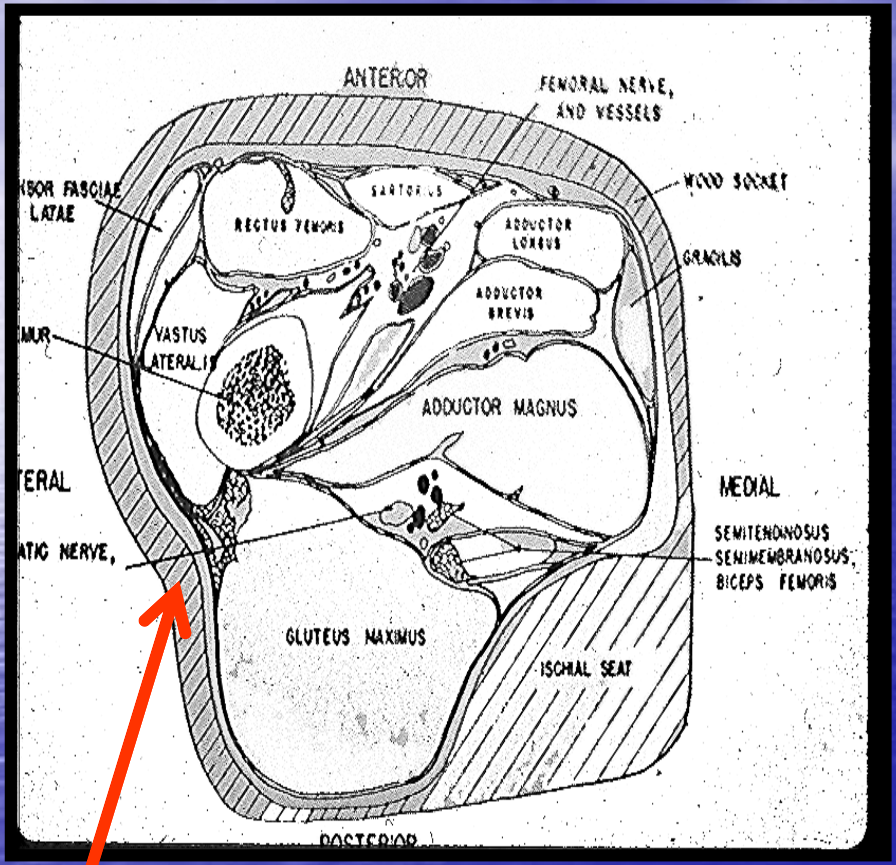
Comparison of Methods for Creating a Lateral control of the femur.



Canty

Sabolich

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MAS Socket

The New Design

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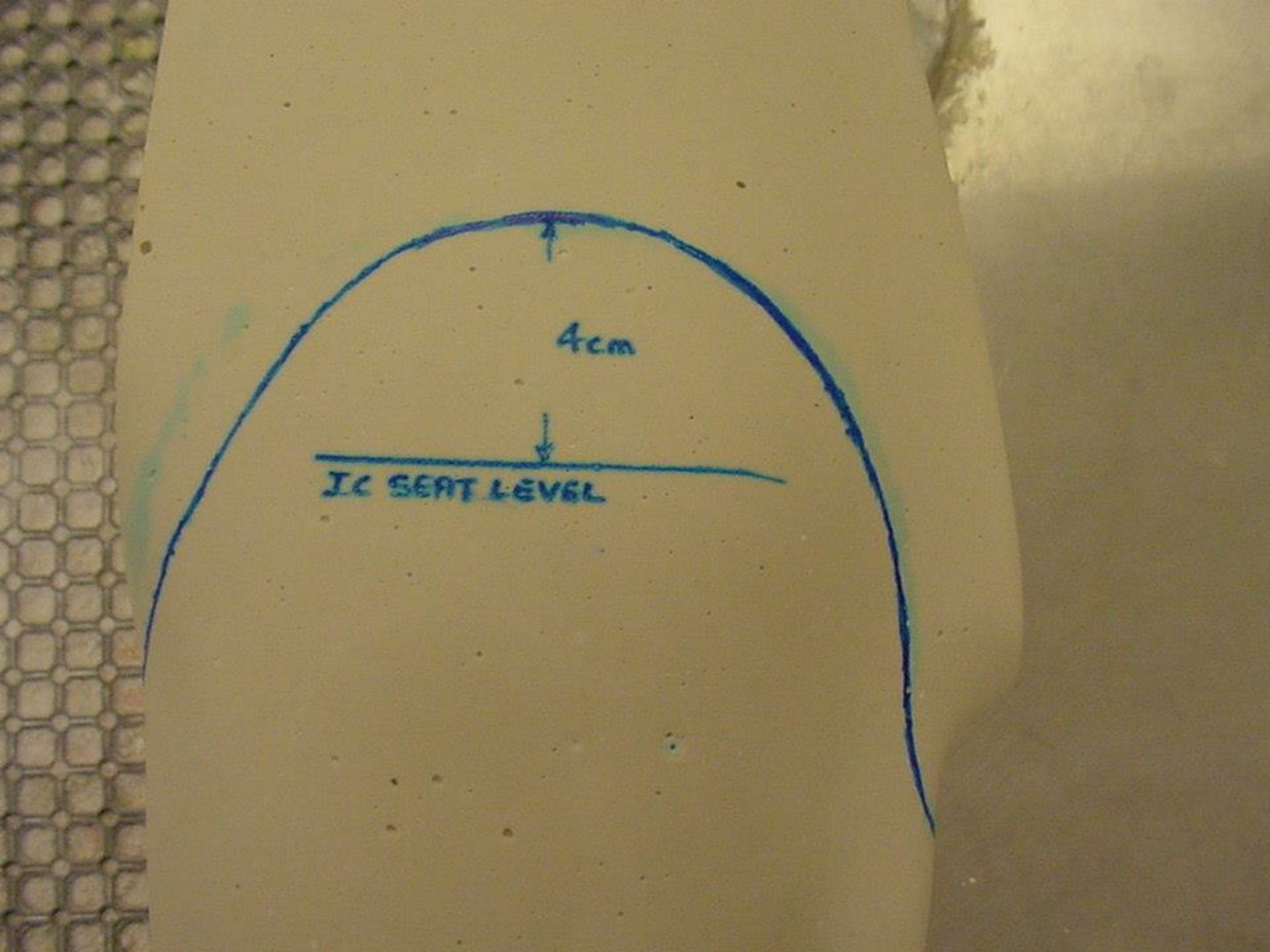
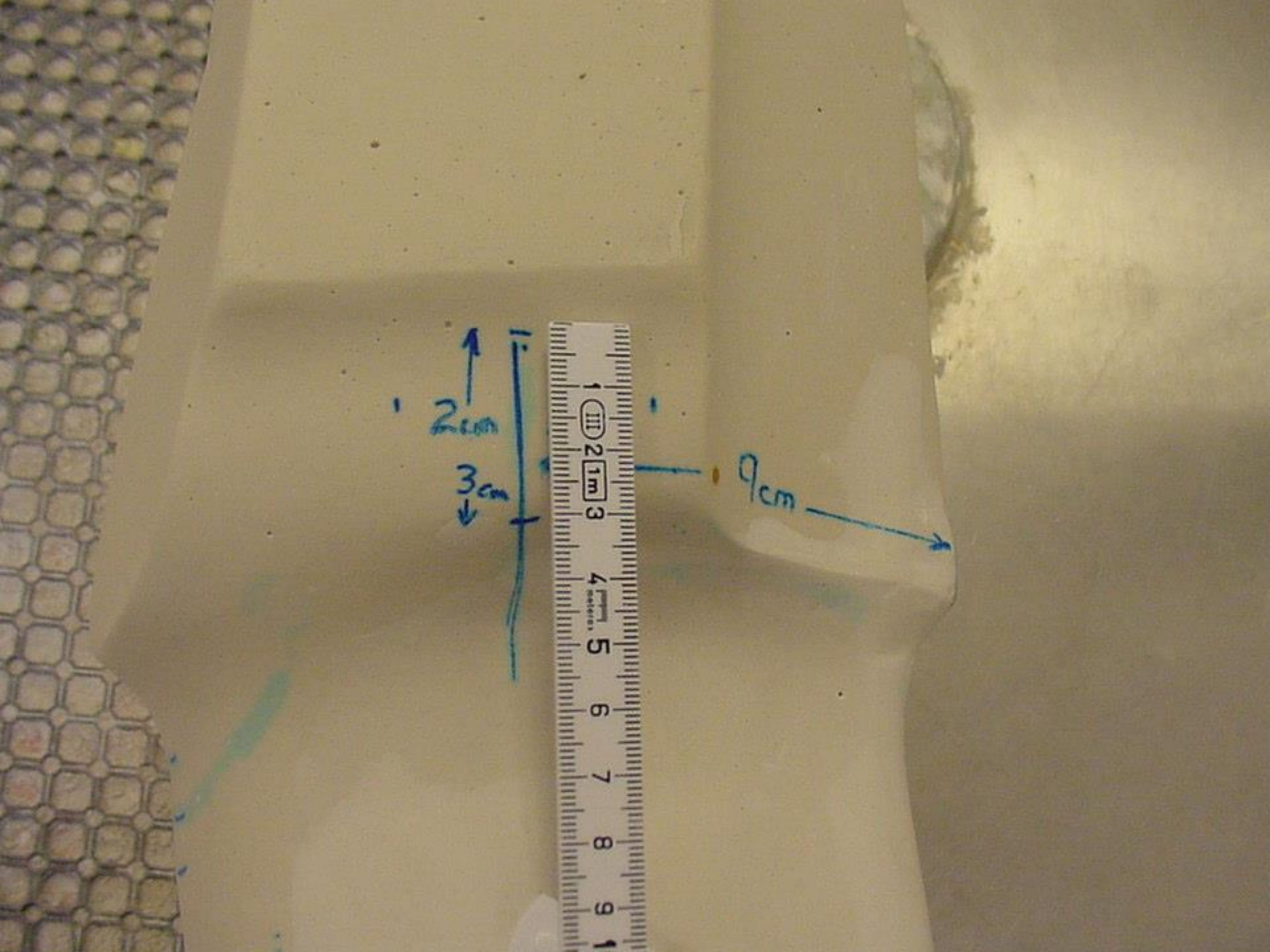
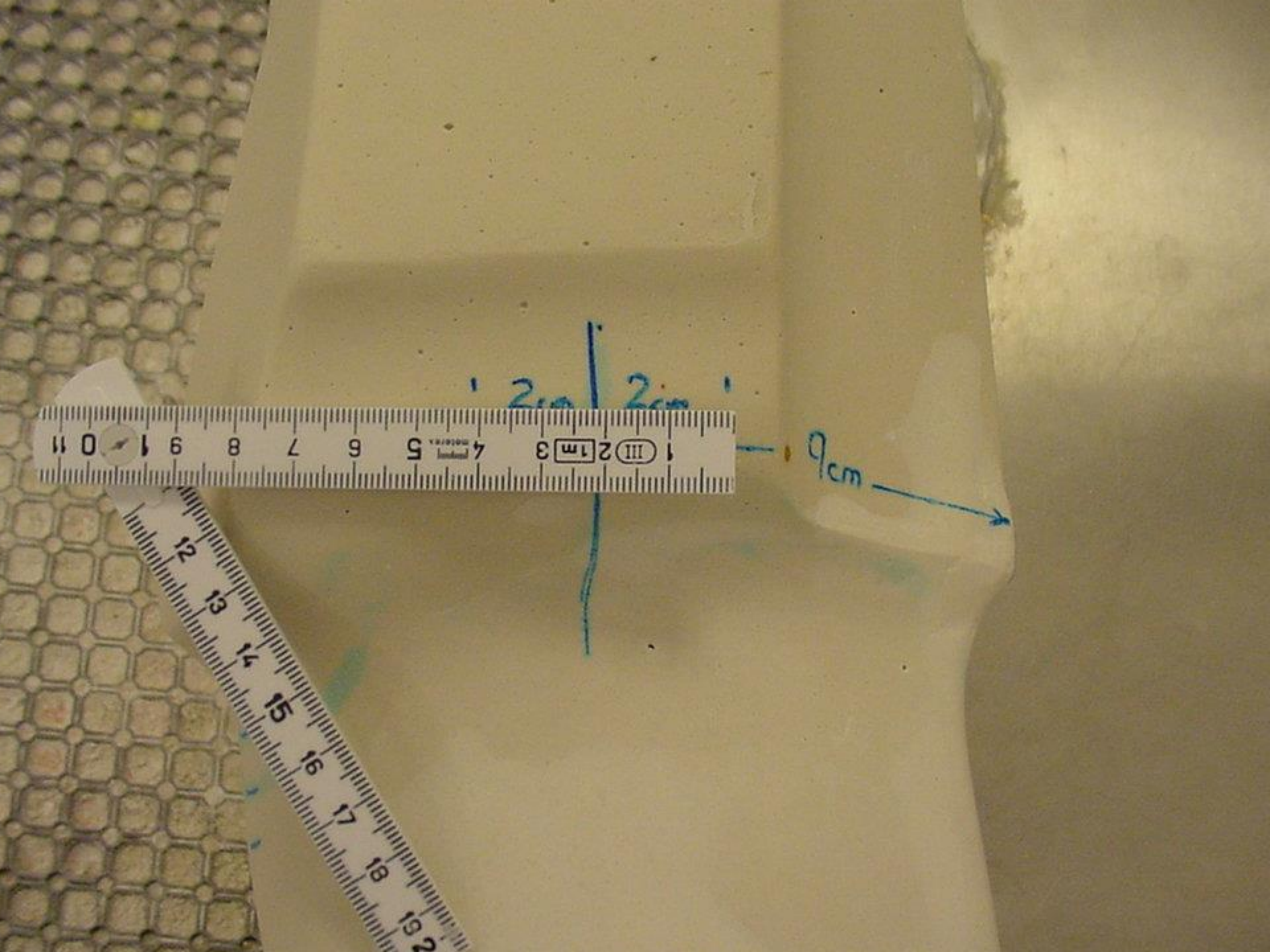
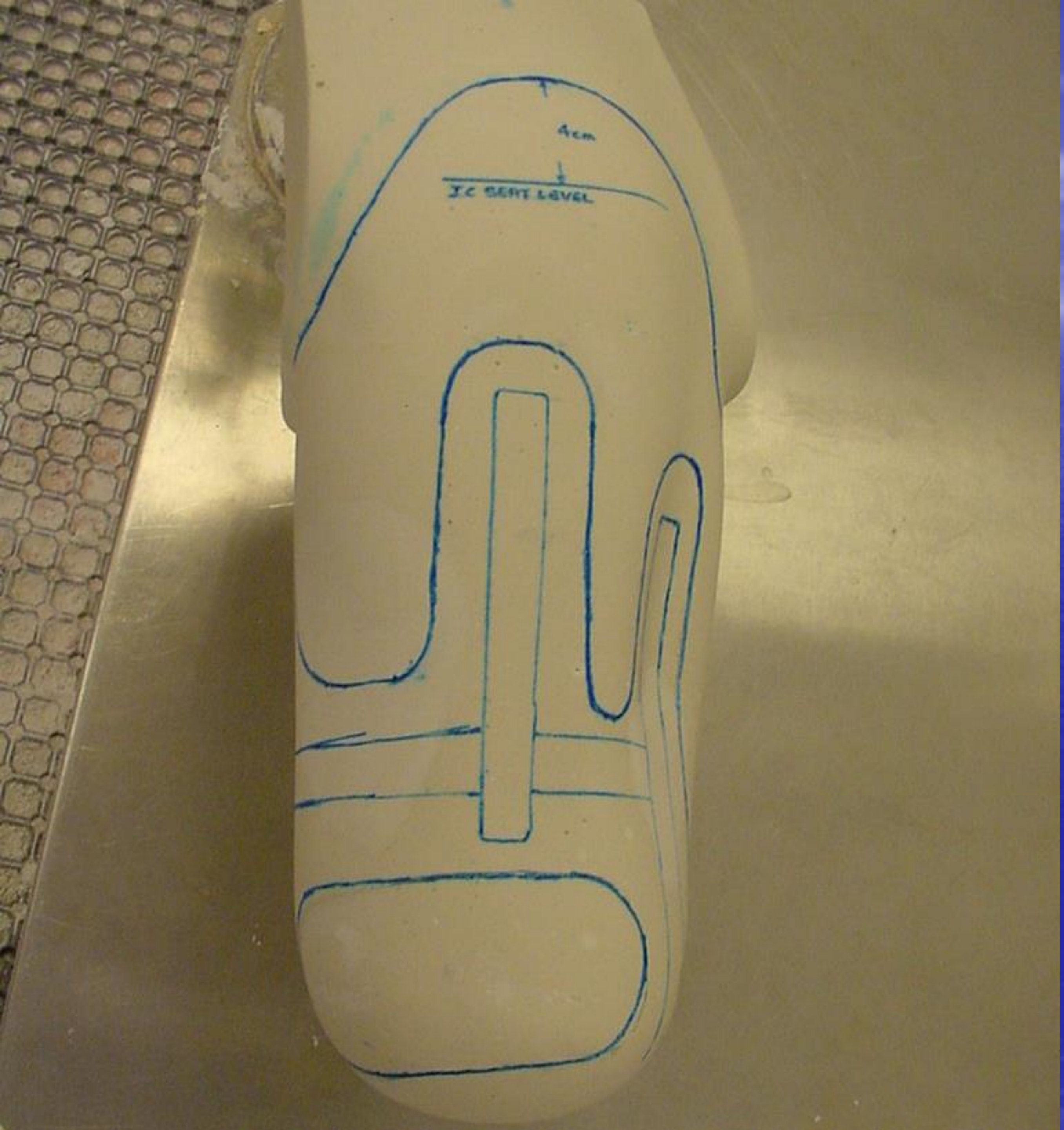

4cm
IC SEAT LEVEL


SHORT
LONG


2cm
3cm
9cm


9cm


2 cm
2 cm
3 cm
9cm



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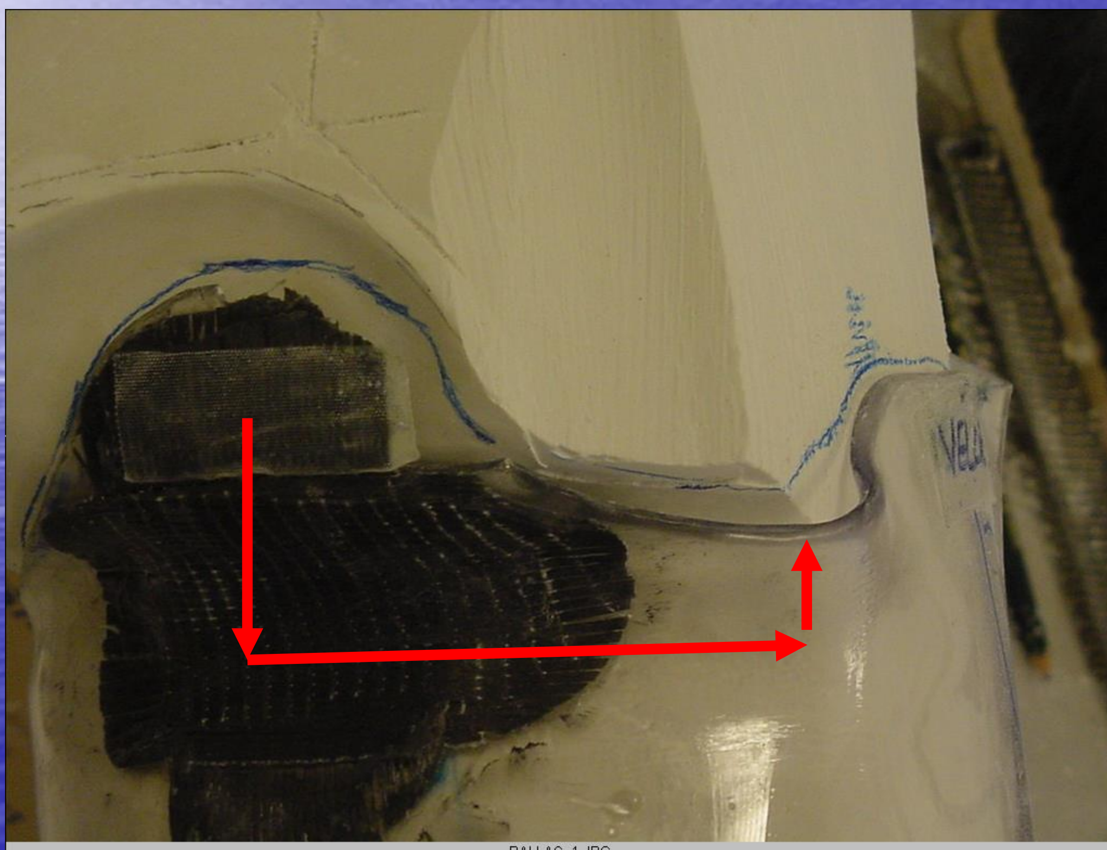
Evolution of the Transfemoral Socket



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Evolution of the Transfemoral Socket

PALLAC~2.JPG

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Evolution of the Transfemoral Socket

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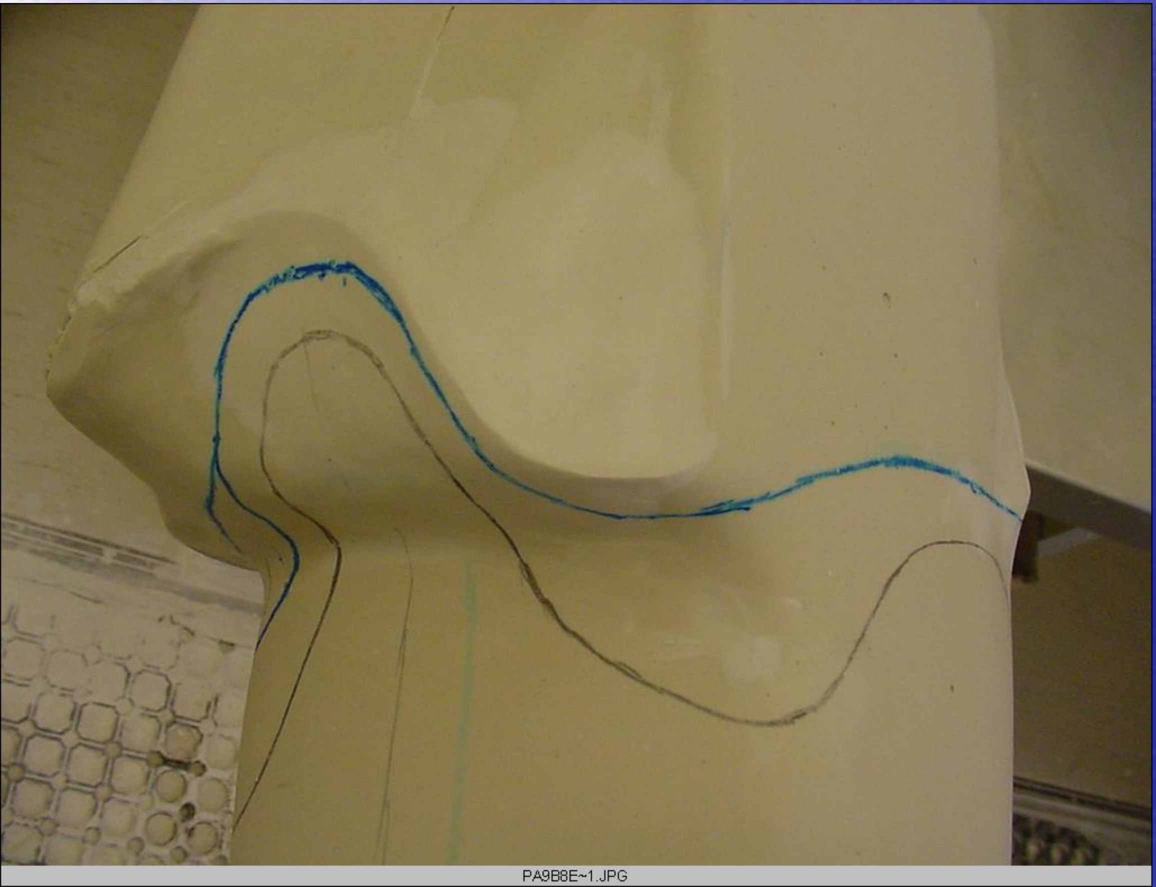
Evolution of the Transfemoral Socket



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Evolution of the Transfemoral Socket

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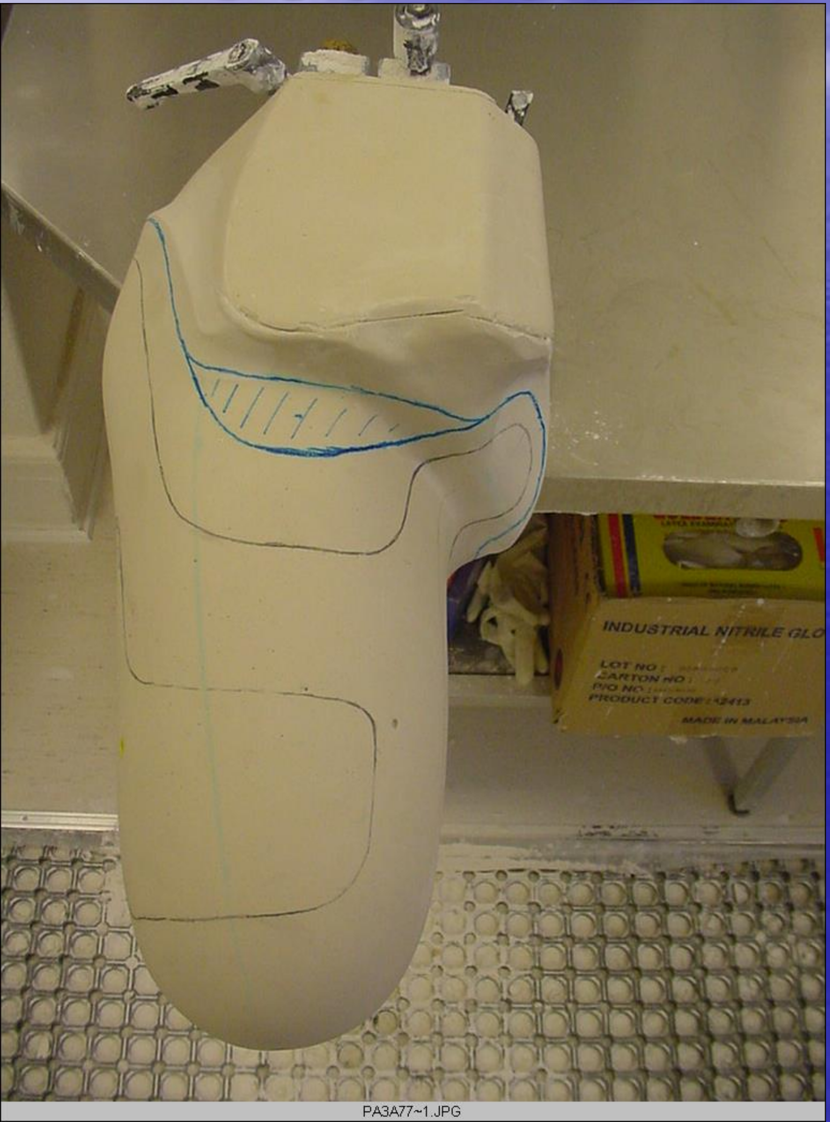
Evolution of the Transfemoral Socket



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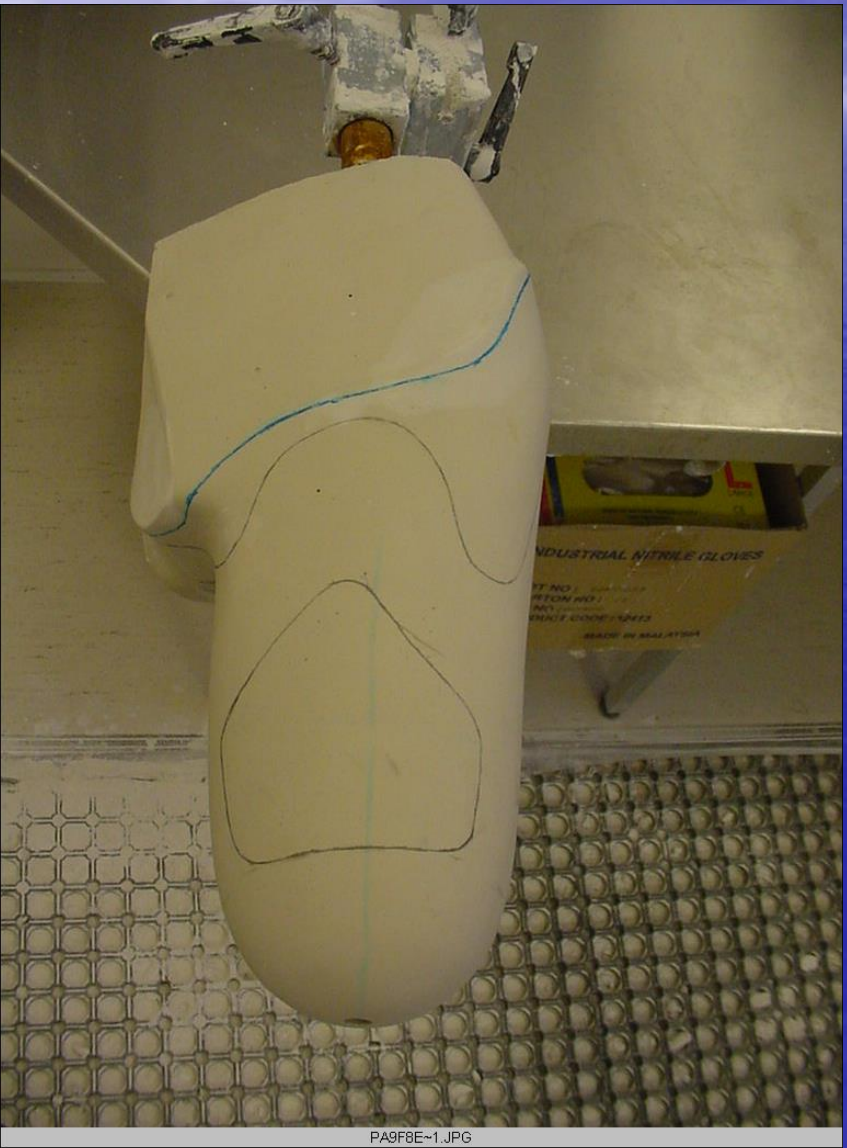
Evolution of the Transfemoral Socket



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Cosmesis

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Cosmesis

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Cosmesis

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Cosmesis

Amputees are still not comfortable – Why?

- Flexible systems not truly flexible.
- Could not adapt to volume changes.
- Could not adapt to shape changes.

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What was missing?

- Truly flexible socket
- Ability to accomodate volume changes
- Ability to re-direct forces

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Second phase – Flexible Socket

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Flexible socket

- ISNY – Otto Bock
- STOD Iceland 1992
- Ossur Iceland
- Pohlig Germany
- Jim & Jeri Grina Texas USA

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The Flexible socket

History

- ISNY Otto Bock.
- Hoyt UCLA - IC Socket.
- Ossur system – Strathclyde university/ STOD
- Otto Bock Silicone House course lead to an interest in cushion silicone liners.
- Which lead to an interest in combining the silicone liner and the support structure from a socket. Thinking along the ISNY lines by replacing the plastic inner socket with silicone a more comfortable socket could be achieved.

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The Idea

- The shape or socket should not expand outside it's volume only allow for shape changes that are wanted and limit the shape changes that are not.
- I introduce shape changes to assist the comfort level and control of prosthesis, for example contouring around the hamstrings on heel contact and the femur to assist the weightbearing area and to give more control to the femur.
- Control of forces on one side might require release of force/ pressure in another area (not necessarily the opposite side)
- Circumferential shape change but not the size.

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The Idea

Many ways to achieve this.

- The current project looks at what is simple, affordable and available.
- Pre-Pregs & Laminations
- Silicone Rolled (extruded) & Laminated

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The Idea

Advantages

- Closely mimics the muscle? / Soft tissues / firm structures.
- Movement and shape changes.
- Can be firm in required areas (Control) and flexible (cushioning) in other, able to fluctuate as the residual limb shape changes.

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Influences.

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A Stretchy Socket For AK Amputees
Jim & Jeri Grina

- “My wife, Jeri, is an AK amputee of over 40 years. About 3 years ago, she wanted a utility leg that she could wear around the house for house and yard work. We obtained a simple leg with locking knee, pylon and Stomper Jr. for her, but as her arthritis began limiting her activity, she gained weight and no longer fit the socket. Our insurance would not cover a new socket, so I began experimenting with socket design.”
- “To accommodate her weight gain, I made sockets of fabric impregnated with urethane. These were easy to fabricate and surprisingly comfortable. Since we developed several sockets of varying rigidity, I made a simple pylon frame to accommodate the sockets. The frame has an adjustable strap on the front, permitting us to place multiple sized sockets in the same frame. The sockets are lined with very soft urethane, which feels like a latex surgical glove, and

  the outer fabric is impregnated with firmer urethane. The two layers are then bonded together. So far, the softer I make the sockets, the more comfortable they are.”

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Simon

Simon

First Try

- **Alpha Liner – Could not function, could not walk.**
- **Iceross Transfemoral liner, reflected back – Could function and walk for limited period – 1 Hr**
- **Iceross Transfemoral liner, cut 1cm above the brim – could function for 3 to 4 hours**
- **Simon rejected all three**

Reason – Suspension failure, socket comfortable.

The Flexible socket

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Lars

Bilateral amputee

Left Transfemoral

Right Symes

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Third phase – Volume management.

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A number of volume management systems have been introduced.

- Pump It Up
- Pneu-Fit
- IPOS
- Active Control System
- Otto Bock – Harmony
- Rincoe Socket Fitting system (Pressure sensors)

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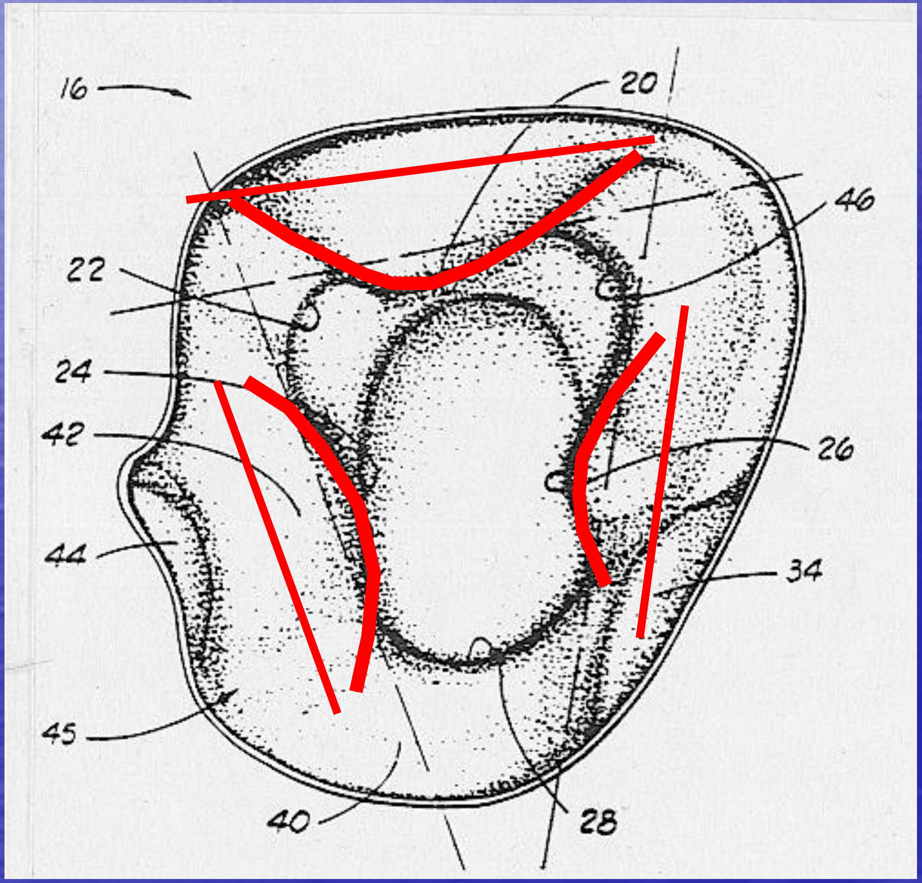

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The needs of the paitients and the Aims of the new socket system

To achieve a socket system that can –

- Use all available parts of the anatomy for suspension.
- Take weight on weight bearing surfaces.
- To give as much control to the prosthesis as is possible.
- To give as much feed back.
- To improved proprioception.

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The needs of the paitients and the Aims of the new socket system

- In all amputation levels there is a degree of instability caused by the amount of soft tissue in the residual limb and by the conditioning of the soft tissue (muscle groups).
- The greater the soft tissue and the lower the conditioning, the lower the control available to the sockets and therefore to the residual limb.

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The needs of the paitients and the Aims of the new socket system

- However even in the residual limb with low soft tissue volume (example a Symes amputation) where there are larger areas with low tolerance or are intolerable to pressure. The greater the need for cushioning and suspension.

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Problems with other systems

- There is no system currently, that is interactive and allows a flow of pressure between cells.
- Only two with a flexible outer socket, these are both Icelandic.
- Air cells are not usually custom made and not incorporated into the flexible systems.
- No monitoring of pressure.
- Cannot self inflate - All cells loose pressure in the first 5 minutes and need re inflation.

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Donning & Doffing

- Deflate cells / system, even using negative e pressure from the reverse cycle of the pump. (To deflate cells with spacing materials in foam/ silicone spacing materials).
- Then don the prosthesis either by inserting the residual limb until comfortable – or using a conventional method to draw the residual limb into the prosthesis – very gentle.
- Possible to use a lubricant to don the prosthesis – this may help the prosthesis to slip off again!!!
- The reverse applies for Doffing.

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Silicone Pros and Cons

Pros:

- Inexpensive
- Easy to manufacture
- Easily available
- Easy technique – Rolled (extruded) and laminated

Cons:

- Skin rashes
- Skin blistering
- Skin breakdown (infection)
- Low durometer not easy to manufacture

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Problems & Solutions

- Tissue Loading – Damage can occur at 8kpa

  Daly CH et al

  The Effect of pressure loading on the blood flow rate in human skin 1976
- Therefore - Inflatable inserts need to be designed specifically to spread the required pressure over the required area. Example, to control the femur.
- Presently the size of inflatable inserts are probably too small and usually uniform in shape. This means that it can only inflate like a balloon in one direction.
- By custom making the inflatable insert it should be possible to limit expansion in certain areas and allow extra expansion in other areas.
- How? Using a foam/ silicone filler in the inflatable insert that adheres to both sides of the insert.
- This could be a foam or strings of silicone placed in the inserts.

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Fourth phase – Interactive Socket.

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The Aims of the new Interactive socket system

- Suspension – improved.
- Volume control – dynamic.
- Comfort – in donning, doffing, sitting, stance and swing phase.
- Stance & Swing phase – areas of pressure change during the gait cycle to the optimum levels.
- Dynamic control – at all times, during the gait cycle and sitting.
- Static control – standing & sitting.
- All amputation levels – Hemi pelvectomy to Symes.

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Inflatable Inserts

Reasons why Inflatable Inserts are used.

- Today: to adjust for volume change
- Tomorrow: To adjust for volume change

AND

  - To Increase the total contact fit – Reason the patient can don the Prosthesis relatively stress free (Pulling in ect.) To inflate the cells to the required comfort levels and obtain the optimum total contact/ weight bearing fit. – This is very important when using the flexible/ Expanding socket, as the forces need to be known and then designed for, so that the pressure contact area and best prosthetic control can be achieved.
  - Low-pressure tolerance areas can be (accommodated) cushioned by the inflatable cells.

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Socket pressure mapping – Dynamic and Static.

- Variable – Constant / pressure – Pressure monitoring & adjustable (blood pressure system).
- Pressure mapping can give a map of required pressure areas for transfer of pressures to desired areas.
- Pressure in (weight bearing).
- Pressure out (pressure redirected to desired areas).
- Allows Hamstrings (gluteal muscle group) and Quads to expand and contract during the gait cycle.
- Real time (depending on the sampling rate).

Gait cycle

- Certain pressures always changing.
- Need for higher pressure areas & lower pressure areas and.

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Problems & Solutions

- All inflatable inserts should be able to be interconnected this interconnection could be isolated, if required, i.e. individual cells that are not connect to the interactive pressure system. It could also be using valves that some cells have higher pressures than others, for example medial and lateral might require a lower pressure than ant / posterior, it might be that two interactive systems work together or independently.
- Manual system that has valves that let in pressure or let out pressure. The high-pressure cells release pressure into low-pressure cells and than when the pressure exceeds a set level in the lower pressure cells the valves release the pressure out of the system (as a comfort and safety measure).

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The manual system

- Has a hand pump or an integrated pump (Reebok shoes, Pohlig/ Otto Bock system and others).
- Low-pressure valve setting & over inflation release valve.
- High-pressure valve setting & release valve into lower pressure cells.

The Automatic system

- Integrated pump – possibly a variation of a blood pressure monitor pump.
- The Automatic system is the same as the manual system however should be computer controlled with a monitoring system, to keep pressure in the cells at the required setting (interactive even during the gait cycle, adjusting for standing and sitting by monitoring these.

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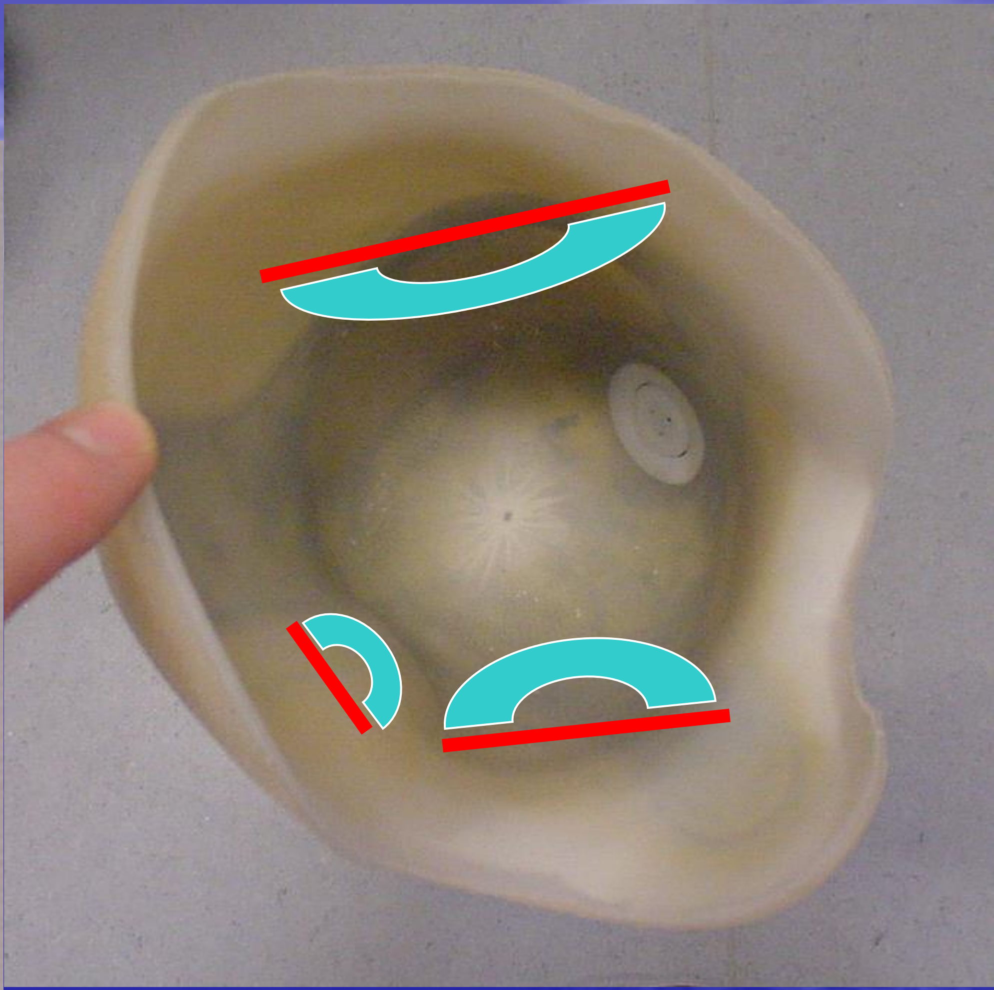

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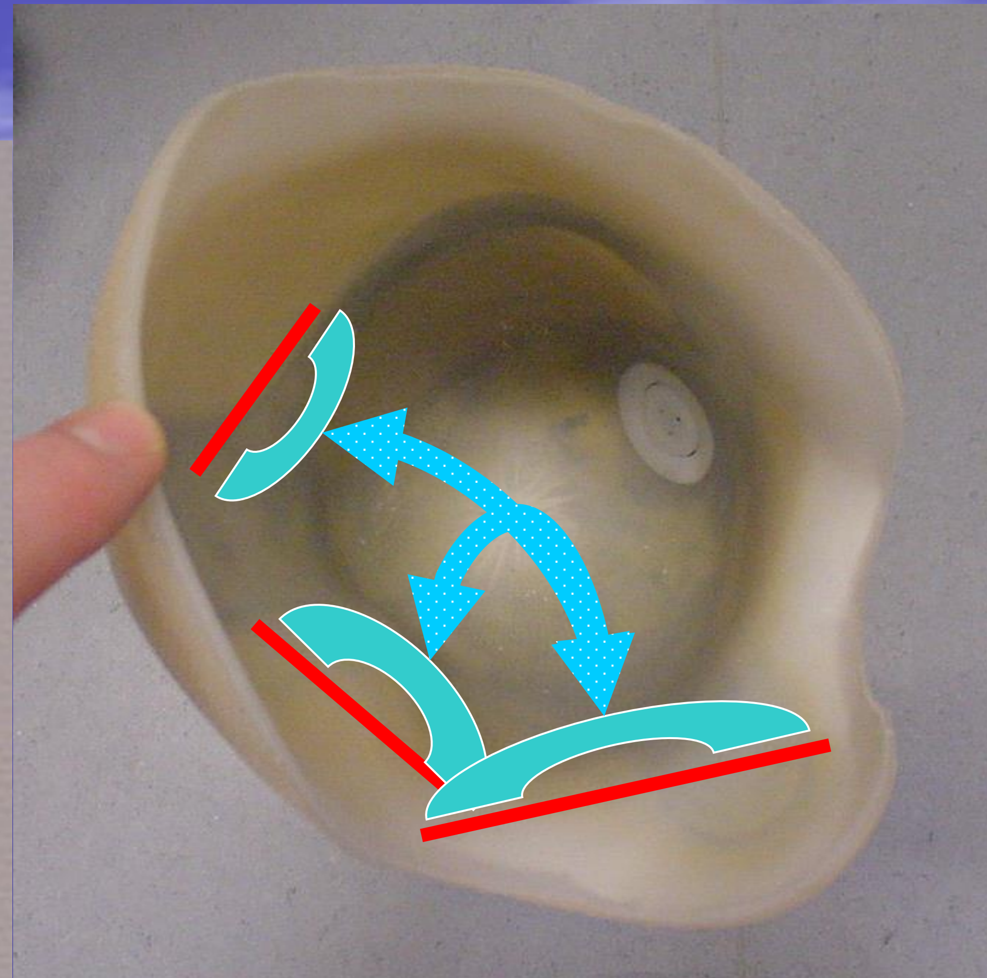

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Problems & Solutions

Strangulation of the Residual limb after inflation. How to overcome this, design of the inflatable inserts? Use of pressure monitors that monitor the pressure of the residual limb and automatically adjust according to the individual patients requirements. A Blood pressure type monitor could serve this function. This could be done at set intervals - this is part of the design that would need development to see if it is viable. If it is, it could be an asset when dealing with primary amputees and vascular amputees, or other patients requiring long term monitoring. This could be linked to a data monitor for downloading (wireless) (a wireless system could also be used to program each patients system and could be used by the patient to vary the setting as required).

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The Market

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Hip Disarticulation

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Knee Disarticulation

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Diagnostic Socket TF

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Diagnostic Socket TF

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