applied human aesthetic in artificial limb design
research design development study

masters industrial design

development study
massey university college of creative arts
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Daniel Buxton BDes (Hons)
2005

“form follows function - that has been misunderstood”.

“form and function should be one, joined in a spiritual union.”

Frank Lloyd Wright.

acknowledgements

I wish to acknowledge and thank the following people whose direction and input during this study has been invaluable.

Kylie Simonsen whose patience is now legendary, Bill and Jenny Buxton, whose support and wisdom has guided me throughout this project and life. Professor Duncan Joiner for managing to interpret and direct me through a stack of chaotic mumbling's. Senior Lecturer Geoff Hargreaves whose design research methodology is light years ahead of its time. A special mention must be made of Marion Lineham from the New Zealand Artificial Limb Board, I could not have ever achieved this study without her help. Ray Binnet and the staff at the Wellington Artificial Limb Centre. Peter Allen my technical advisor and Jose for spending his valuable weekends editing my work and putting up with my lip.

declaration

This thesis titled Applied Human Aesthetic in Artificial Limb Design is presented in partial fulfilment for the degree Master in Industrial Design.

Daniel Buxton. 2005.

V

abstract

fig.1

This abstract provides the reader with a brief overview of this Industrial Design Development study.

The term Industrial Design is one that will not be readily recognised within the prosthetic industry around the world. One branch of Industrial Design is the application of 'humanistic factors' to product research, development and design. The visual aesthetic form of current artificial limb design appears to deliver an inconsistent communion with the functional criteria. This engineer dominated industry is motivated by product function while seemingly lacking consideration for factors like human/machine interface, comfort factors and natural structural form.

The physiological expectations and user requirements of an amputee progressively dictate the functional advancements in research and development, and thus artificial limb research and development is at the forefront in robotic industries, material development and to a varied extent man machine interface systems.

> 'We've got to this international place in the world and I think that if we are going to do anything in New Zealand in the way of design, we have to first become jolly good designers.'
>
> Coe, J. (1972). (Interview). Nees,G. Five characters in search of a style. Designscape.33:2.

> 'Why don't we make artificial limbs that are not stumps or broomsticks?'
>
> Coe, J. (1972). (Interview). Nees,G. Five characters in search of a style. Designscape.33:2.

In today's commercial environment there appears to be a growing demand for lower extremity prosthetic extensions that replicate the function of of the limbs being replaced. The artificial limb is a complex piece of equipment. Modern research and development processes are orientated towards an engineered functional outcome. Do current research and development processes place less consideration on the missing *humanistic* form than the function?

fig 2

What we are now seeing in research and development is micro-processor technology being integrated into the limb to control preset dynamic movements. This technology has greatly contributed to the mobility of thousands of amputees who otherwise would have been wheelchair bound.

What is missing?

The answer is the humanistic touch. We are now witnessing an overload of technological advances without any real consideration of the human aesthetic. Form has taken a back seat to the functional attribute. While functional values are of great importance, form should by no means be neglected.

'Possibly we should produce international artificial limbs and Maori artificial limbs?'

Athield, I. (1972). (Interview). Nees,G. Five characters in search of a style. Designscape.33:2.

The process of artificial limb attachment (suspension) requires the prosthesis to be attached to the existing 'residual limb'. The favoured and most accessible avenue for a transtibial (below knee) amputee is to use either a Urethane sleeve or a Vacuum Socket. These methods though successful, do not provide the residual limb with a habitable environment.

Herein lies the dilemma. While an amputee is able to re-establish certain lost movements, both the humanistic and physical/physiological barriers remain. Aesthetic form is relegated to a distant second place. For some the absence of the aesthetic may be as devastating as the inability to function normally.

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1.0

introduction and background to study

The transtibial or below knee artificial limb is a relatively simple product. It does not contain any moving parts. It is made from strong materials that are both durable and reliable. It is simply constructed, takes little time to produce but is highly engineered.

It is a very intimate product for users, and can cause either pain or pleasure depending on its interacting with the user. While the functionality of this established product drives the direction of its design development, the notable lack of visual appeal is surprising especially given the intention to create a product that shows an intimate relationship with the user. The type of transtibial artificial limb a user receives will depend on a wide range of criteria, ultimately a prosthestist will make the final decision.

This study has arisen from an absence of identifiable human qualities in artificial limb design final formed aesthetic product. The humanistic qualities missing include the human/machine interface and the functionally dominated industry the product derives from. 'Products for people with disabilities are inferior to consumer products in the mainstream markets' (Allen, 2002). Currently product emphasis is on maintaining a very high standard of functional engineering. However product aims in this field are inconsistent with the visual qualities of both the limb being replaced and to a certain extent the extended human form that it represents.

'Maintaining a designed visual quality that incourages interaction' (Buxton, 2003). The human/machine interfacing qualities are considered at best average, however an engineered high-quality visual aesthetic is recognised. Current artificial limb product form, function and interface require a set of instructions based on an individual's particular ergonomic measurements. In the case of a transtibial amputee, exact measurements of the stump (residual limb volume), shape gait, stance and swing phase are required prior to an amputee being fitted with the artificial limb.

The overall universal characteristics of the human leg mean that standard artificial limbs can be manufactured, with variations made to suit the specific requirements of an amputee. This is important because measurements always vary from individual to individual.

The emphasis on functionality in the field of artificial limb design suggests a current lack of understanding of:

- the interaction between the human and machine;
- cultural identification;
- exo-skeleton design development;
- the required visual balance between the product form and its relative functionality.

This study is based on 'Applied Human Aesthetic' industrial design theory to the prosthetic industry, a discipline industry heavily dominated and reliant on an engineered field of research and development.

A suggested point of departure for this study is found in current state of the art manufactured transtibial limb sections available in today's marketplace. Identifying and reviewing product data from similar ranged products will provide a starting point from which current functionally found products and their designed forms, can be identified and potentially developed by applying a human aesthetic methodology.

2.0

central proposition

The central proposition of this research design and development study is that by applying an APPLIED HUMAN AESTHETIC design methodology to artificial limb design, the aesthetic preference and values of transtibial amputees can be established and applied to a transtibial artificial limb.

2.1

project aims

The aims of this project are to:

- Identify the basic humanistic aesthetic issues, transtibial amputees identify with their artificial limb(s) via a qualitative questionnaire.
- Apply a suggested APPLIED HUMAN AESTHETIC methodology to the transtibial artificial limb exo-skeletal design and development.
- Design and develop a zip-on transtibial sectioned exo-skeletal artificial limb that applies an amputee's natural form without jeopardising functional criteria.
- Implement a material-based development study to identify suitable laminate composites and memory alloy mesh combinations.
- Design and develop an exo-skeletal transtibial artificial limb.

2.2

industrial design research objectives

The industrial design research objectives of this study are to:

- define active transtibial amputees' aesthetic preferences regarding their artificial limbs via a qualitative questionnaire; and
- apply an 'Applied Human Aesthetic' methodology to this transtibial artificial limb design and development project.

2.3

industrial design development objectives

The industrial design development objectives of this study are to:

- develop a conceptual zip on operational attachment (suspension) system;
- develop a breathable residual limb environment;
- develop a transtibial exo-skeleton blueprint design;
- develop carbon fibre and memory mesh alloy lamination;
- prototype a transtibial artificial limb.

2.4

ethical standards

This describes the ethical guidelines followed for this research design development study Applied Human Aesthetic in Artificial Limb Design.

During the course of this project, ethical issues regarding the use of test subjects and their interaction with their prostheses were expected to be raised. In the interests of participants in the questionnaire conducted for this project, a very high standard of ethical conduct was maintained at all times.

To manage these high ethical standards and expectations the following list of major ethical principles were adhered to (as outlined in Massey University's, Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants).

Ethical principles considered during the course of this study were:
a) respect for persons;
b) minimisation of harm to participants, researchers, institutions and groups;
c) informed and voluntary consent;
d) respect for privacy and confidentiality;
e) the avoidance of unnecessary deception;
g) social and cultural sensitivity to the age, gender, culture, religion, social class of the participants; and
h) social justice.

At no time during this design and development study were issues regarding Maori, iwi or The Treaty of Waitangi affected. This also applied to other ethnic groups residing within New Zealand.

- At no stage during this design development study were any participants, researchers, institutions and groups unnecessarily subjected to risk or harm.
- All participants were adequately and appropriately informed about the study, their participation in the questionnaire and consents and privacy.
- A written consent and privacy statement was provided to consenting parties before any further action was undertaken.
- At no time has any participating individual been identified without his/her prior approval.
- A confidentiality agreement had to be signed by both parties before any participation could take place.
- The confidentiality of all information obtained during this design development study was and will be respected.
- During the research design development study care was taken to avoid any unnecessary deception.
- A no time did the use of students in the initial stage of the project interfere with their school work, line of study or university attendance. Avoidance of conflicts of interest was taken very seriously at all times.
- At no time were children or minors (anyone under the age of 18) used during this study.
- No form of community-based research was required for this study.
- Adequacy of Research. The researcher/designer undertook to achieve the outlined goals of this design development study at all times. The researcher/designer being qualified in the appropriate field responded according to his Supervisor's guidance at all times.

2.5 RESEARCH TIMEFRAME

- Applied Human Aesthetic in Artificial Limb Design proposal
- Innovations for Quality Living, Poster presentation, Hong Kong. ISPO.
- Contact New Zealand Artificial Limb Board to arrange presentation
- Research financial grants for study
- Initial contact & identification of industry experts
- Initial contact & identification of subjects
- Industry expert group establishment
- Establish contact Wellington Artificial Limb Centre
- Formulate transtibial amputee participant group
- Permission, privacy and confidentiality agreements
- User group interaction and discussion, initial concepts
- Review of initial key findings
- Pilot questionnaire proposal and permission
- Massey presentation
- Questionnaire formulation
- Massey University Ethics application
- NZ Health and Disability Ethics application
- Concept generation rendering development
- NZALB staff presentation concept development review
- Expert development evaluation
- Product process 'state of the art' review
- Concept generation prototype development
- Massey presentation
- Draft report
- Trial subject initial questionnaire and active interest survey
- New Zealand Artificial Limb Board presentation
- Initial product identification and critique
- Final report

July 04

August

September

October

November

December

January

February

March

April

May

June

July 05

October 05

DESIGN DEVELOPMENT TIMEFRAME

- Product problematic identification
- Design development study aim and goal
- Problem identification research design development
- Myographic drawing leg movements and stills
- Lower leg detailing of muscle groups
- Design development transtibial section
- Model drawings and design
- Produce negative leg mould box
- Negative leg plaster casts from leg model for pre-prototyping
- Positive plaster leg moulds construction
- Plaster transtibial model casting
- Negative transtibial leg mould construction
- Positive lamination transtibial moulds
- Initial prototyping material identifications
- Material lamination development
- Prototype material collection
- Zip on attachment prototyping
- Model drawings design development
- Transtibial attachment section design development
- Transtibial fin design
- Lamination form design development
- Fibre composite leg model rapid prototyping
- Fibre metal laminate prototyping
- Ankle joint design development
- Final modeling prototype
- Final prototype

table 1

research design and development timeline

3.0

research design and development methodology

Industry technical expertise
- qualitative research
- expert technical opinion
- interface environment
- prosthesis fitting process
- product research
- industry networking
- industry production analysis

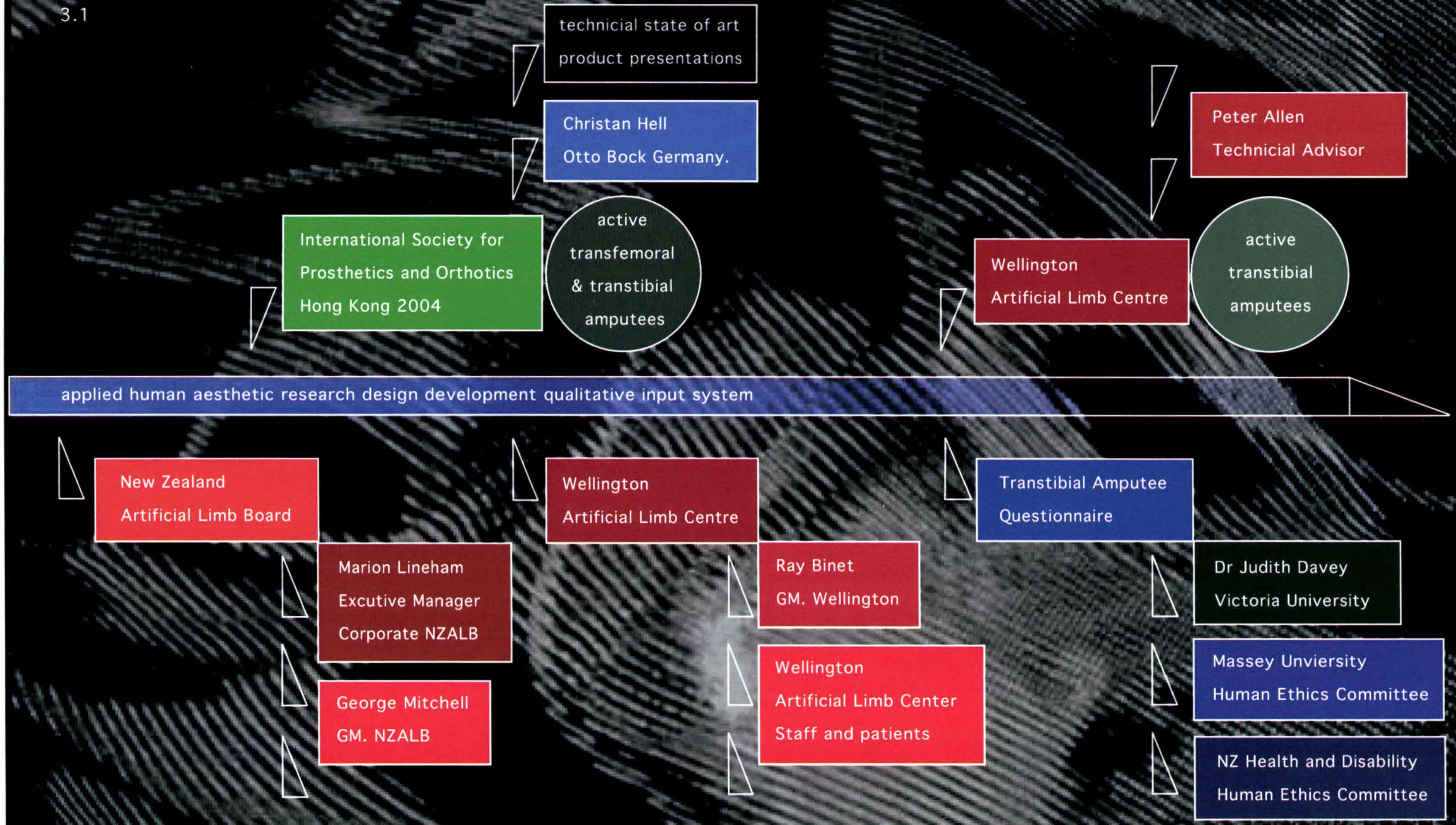
Objectives
- problem identification
- analysis feedback
- concept resolution
- materials research
- product development
- NZ patent

Active transtibial amputees
- qualitative questionnaire
- user opinion
- individual experiences
- product dissatisfaction
- operational problems
- user ideals
- suspension attachment
- interest & goals

Concept design development
- state of art product applications
- ergonomic motion study
- materials and lamination analysis
- concept design development
- artificial limb prototyping
- suspension (attachment) research

table 2

3.1



technicial state of art
product presentations

Christan Hell
Otto Bock Germany.

International Society for
Prosthetics and Orthotics
Hong Kong 2004

active
transfemoral
& transtibial
amputees

Peter Allen
Technicial Advisor

Wellington
Artificial Limb Centre

active
transtibial
amputees

applied human aesthetic research design development qualitative input system

New Zealand
Artificial Limb Board

Marion Lineham
Excutive Manager
Corporate NZALB

George Mitchell
GM. NZALB

Wellington
Artificial Limb Centre

Ray Binet
GM. Wellington

Wellington
Artificial Limb Center
Staff and patients

Transtibial Amputee
Questionnaire

Dr Judith Davey
Victoria University

Massey Unviersity
Human Ethics Committee

NZ Health and Disability
Human Ethics Committee

table 3

qualitative research design and development feeder system network

4.0

new zealand artificial limb board

The New Zealand Artificial Limb Board (NZALB) is a Crown entity, a national prosthetic limb service to New Zealand amputees. The New Zealand Artificial Limb Board's aim is to provide amputees with 'mobility' and facilitate their 'induction' in the use of their artificial limbs. It also provides a service for the fitting and maintenance of prosthetics and other related services.

The defined functions of the New Zealand Artificial Limb Board are to:

- manufacture, import, export, market, distribute, supply, fit, repair and maintain artificial limbs;
- provide rehabilitation and other services to persons with artificial limbs and similar devices;
- carry out research and development in relation to artificial limbs and similar devices;
- advise the Minister of matters relating to artificial limbs and similar devices.

The key Government goals which the New Zealand Artificial Limb Board contributes towards are:

- maintain trust in the Government and provide strong social services;
- reduce inequalities in health, education, employment and housing.

The New Zealand Artificial Limb Board's objectives are to:

- provide a comprehensive rehabilitative service;
- deliver culturally appropriate services;
- operate as a successful enterprise;
- access/participate in international research and development;
- maintain forefront technology and cutting procedures;
- develop a confident, innovative and energetic, publicly-recognised organisation.

4.1

new zealand artificial limb structure

There are five New Zealand artificial limb centres located around New Zealand, in Auckland, Hamilton, Wellington, Christchurch and Dunedin. These centres are also responsible for servicing their localised outlying areas.

Due to demands of amputees, the NZALB provides a range of services that include:

- prosthetic consultation services;
- orthopedic surgeons;
- physiotherapists;
- occupational therapists; and
- prosthetic artificial limb fitting and maintenance services.

The fitting and maintenance service monitors amputee's health, physique, activity levels and limb durability. Staff also assist in gait training.

Amputee funding in New Zealand is provided by the Ministry of Health and the Accident Compensation Corporation. A small number of war amputees are funded separately as are special individual cases. An example of this is Mark Ingis and his specialised artificial limb requirements. Cooperation with other organisations associated with amputees such as, District Health Boards, Amputees Federation of New Zealand and community organisations is encouraged.

4.2

new zealand artificial limb national statistical overview

As recorded on 30 June 2004, there were 4334 amputees registered on the Limbs Information Management Database. 75% were male, 50% were between the age 20 and 59. 77% were European while still covering a very wide range of ethnic diversity. 42% of amputations were trauma related and 54% of all amputations in New zealand were below knee.

'Report of the NEW ZEALAND ARTIFICIAL LIMB BOARD'. (2004). For the Year Ended 30 June 2004. Annual Report 2003/2004. Minister for Social Development and Employment. 59 Adelaide Road, PO Box, 7281, Newtown. Wellington.

sex

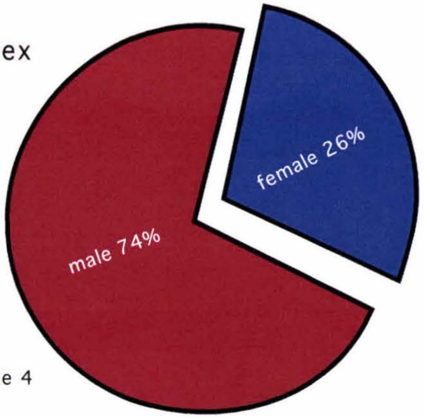


table 4

age

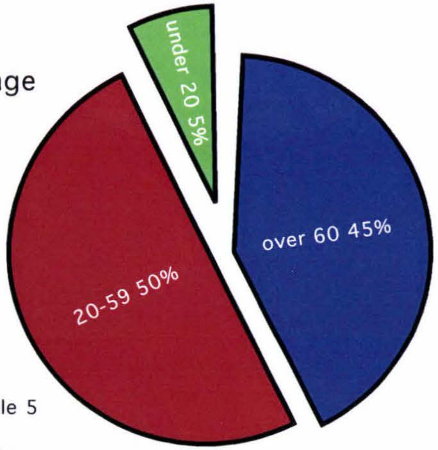


table 5

ethnicity

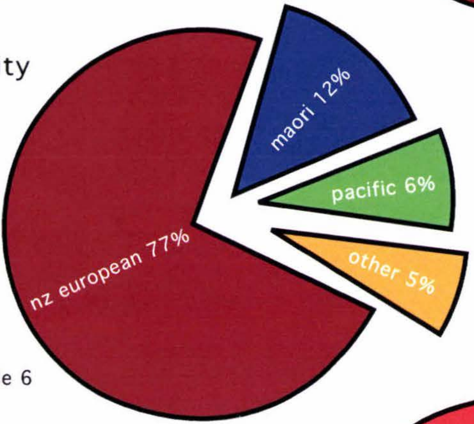


table 6

range

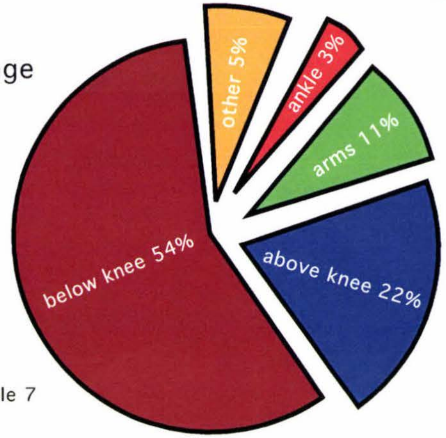


table 7

amputations

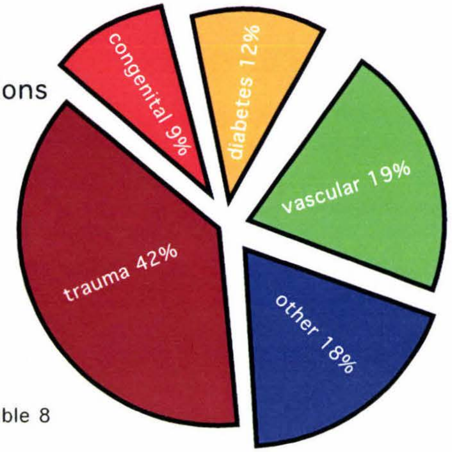


table 8

4.3

transtibial artificial limb industry fitting and production process

Currently transtibial artificial limb fitting techniques are customised to the various requirements of amputees by prosthestists. There is a basic process format that amputees must go through to fit a customised artificial limb. This process is common throughout New Zealand and most first world artificial limb agencies.

The procedure is as follows:

The residual limb volume and shape of the amputee is measured by a three dimensional CADCAM software scanner (figs 3/4). The scanner measures the total residual emersion socket area and produces a three dimensional image on the computer using the CADCAM software (fig 5). It is critical to establish an exact measure for a perfect socket fit. Residual limb volume fluctuations can vary due to a patient's body temperature, blood pressure and the recovery stage after post operative proceedures. Once the residual measurements are confirmed, a three dimensional form core mould is produced using a 3D router (fig 6). This produces an exact replicated foam form of the residual limb (stump) (fig 7) from which the external socket is then moulded.


fig 3

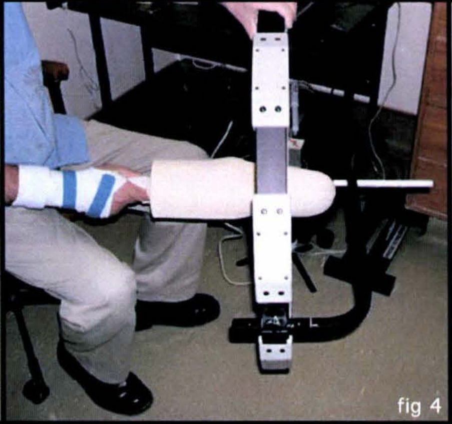


fig 4


fig 5

fig 6

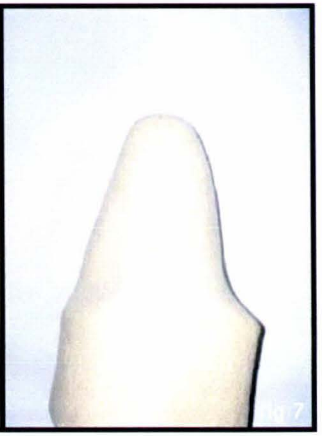


fig 7

4.4

the artificial limb product concept overview

fig 8

fig 9

Aim:

The aim of this research and development study is to form an understanding of the physical and psychological relationships between lower extremity amputee and his/her prosthetic artificial limbs. The findings of this study will form the basis for the redesign of an artificial limb and attachment system.

Objectives:

The project's objectives are to design a natural looking artificial limb and computer controlled attachment system by applying:

- a soft system computer control;
- a breathable attachment interface system;
- a natural visual presence; and
- to design a light weight artificial limb that has multi functional abilities, simply by interchanging various software programmes depending on activity.

Goals:

The goal of this research and development study is to establish and quantify the transfemoral attachment interface requirements of an amputee's prosthetic device. Create an artificial limb attachment interface that can sense, recognise, configure and adjust the attachment requirements to suit the varying ongoing needs of a transfemoral amputee during every day use of an artificial limb.

Discussion:

Remarkably, for the past 50 years, the use of the suction socket artificial limb attachment system has remained unchanged. The suction system is unique as it applies negative pressure on a residual limb to hold it in place. The suction system provides an adequate gait system with motion controls and provides load and force supports. It is however not aesthetically appealing. When fitted with a robotic limb such as Otto Bock's C-Leg the end result provides an amputee with an unheard of degree of freedom. The suction socket provides a very clean attachment process without requiring any straps. Amputees are not required to undergo post- amputative operative procedures to have an attachment unit such as that required in Osseo Integration (affixed to bone) attachment. Artificial limbs currently available vary greatly in price, function, visual aesthetic and weight.

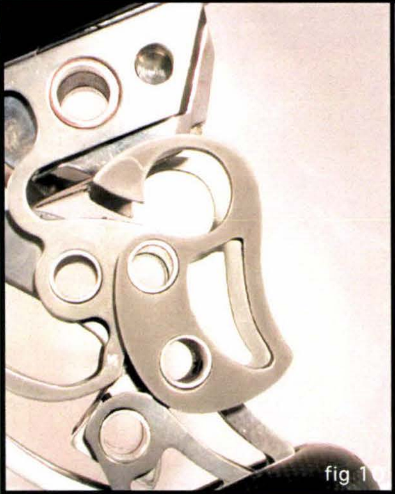


fig 10

fig 11

Design Criteria:

The new form of attachment system developed for this project falls within strict design criteria, such as working within current prosthetic fitting and manufacturing processes. The difference with this new form is the emphasis placed on visual design. As identified by participating amputees surveyed for this study, re-emmersing a residual limb into a foreign environment that does not supply a breathable atmosphere or temperature control has little benefit for the amputee. Instead by providing a friendly environment for the residual limb, amputees are immediately presented with a well balanced relationship with their artificial limb in a way that addresses both their physical and psychological needs.

4.5

initial conclusions
the artificial limb

The following initial conclusions are drawn from the research and development study; Buxton, D. (2003). The Artificial Limb. Massey University School of Industrial Design.

This artificial limb design is based on:

a) the application of a suggested 'Applied Human Aesthetic' theory. The shape and form of an artificial limb designed for this project is based on the leg's muscle structure. The aim is to design an artificial limb using materials capable of replicating the action of these muscles;

b) internet configurable using self-evolving software; the suspension (e-ttachment [internet configurable]), interface socket system can be remotely adjusted by a Prothestist over the internet. The evolving software can sense fluctuations in the residual limb and self-adjust accordingly;

c) a combination of layered material laminates replicating muscle actions and integrated flexible embedded software;

d) current manufacturing processes, utilising common prosthetic construction, connection and fitting processes while enhancing the human/machine interface;

e) an e-ttachment socket shell is constructed from EquiKool (a breathable pressure management system,) carbon/kevlar laminates, embedded Nitinol memory alloy and Softswitch flexible circuitry;

f) the socket shell allowing an even breathable pressure encompassing the residual limb while evenly distributing the applied forces to the residual surface area;

g) a control system managed via the internet. (Softswitch technology allows the monitoring of residual fluctuation over the surface area and temperature controls);

h) a remote CPU system capable of maintaining an even socket grip over the complete residual surface area during various activities; and

i) the CPU system monitoring gait controls and easing the grip on the residual limb while the limb is in 'static phase' allowing the constant circulation of blood within the residual limb.

4.6

ISPO conference
innovations for living
hong kong 2004

The aim of the International Society for Prosthetics and Orthotics Conference is to create a scientific programme that combines prosthetics and orthotics with the theme of 'Innovations for Quality Living'. Held in Hong Kong during the first week of August 2004, 576 presentations were made by a variety of experts in this field from 37 countries.

Students wanting to exhibit their work at the conference were required to submit an abstract outlining details of their work for a display poster presentation. I was one of the sucessful student postgraduate applicants and the only industrial designer out of the 2500 attending delegates.

fig 17

fig 18

During the conference, I was able to refine the scope of my study as a result of feedback from participating experts. All agreed that 'design' is a new area in the current field of prosthetic research. The suggestion of applying a designed form to an a artificial limb was a new idea among those I talked to. While the area of industrial design does exist in the prosthetics arena, it is limited, at this stage, to the requirements of a functional product. There appears to be little movement by prosthetic designers beyond this functional focus at this stage.

The poster presentation (figs17/18) involved displaying details of my project abstract, aim, goal, research methodology and initial conclusions. Time was also allocated to students to present their work, engage in informal

Certificate of Attendance

presented to

Daniel RS BUXTON

for having participated in

The 11th World Congress of
The International Society for Prosthetics and Orthotics

1 - 6 August 2004

Hong Kong Convention & Exhibition Centre
Hong Kong, China

Professor Arthur F.T. Mak
Chairman
ISPO 2004 World Congress

fig 15

discussion with any interested parties and discuss my study in more detail. My model display of a full-sized transfemoral artificial limb caused a bit of a stir and attracted a lot of interest. The model was commended as having a refreshing approach to form in a functionally dominated industry. Some went so far as to request a transfemoral amputee be fitted to my artificial limb, at which point I had to remind them that it was only a model.

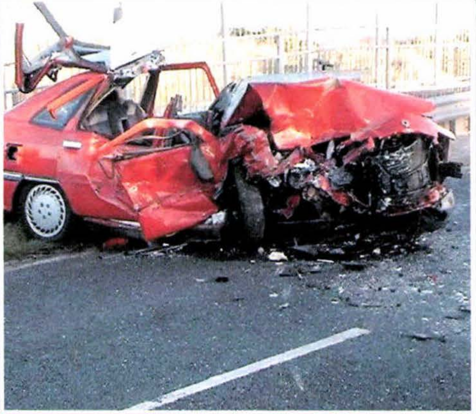
During the conference I was able to ask two female transfemoral (above knee) and three male transtibial (below knee) amputees about the visual appeal of their artificial limbs. The consensus was that little or no thought had been given to the visual form or lack thereof of their protheses, due to the fact that there are currently few options available. I also asked whether by applying natural volume or form to an artificial limb, through design, amputees might increase their relationship, and thus confidence, with their limb. This too had never seriously been considered. It appeared that the artificial limb was not considered as a 'product' by these amputees, but as a practical item of convenience, recommended by a prothestist.

product identification phase

pre trauma

This table represents an individual's interpretation of an artificial limb as a product, pre and post tramua.

product indentification evaluation
- design source
- object transmitter
- sensory sensers
- emotive qualities
- user interaction/reaction



Pre-tramua product interaction; an individual will acknowledge an artificial limb product by its form. This relationship is based on product aesthetic recognition (stimulus).

Post-tramua product interaction; an amputee will become intimate with artificial limb due to function interaction relationship (situation). Visual aesthetic recognition evolves with product function interaction.

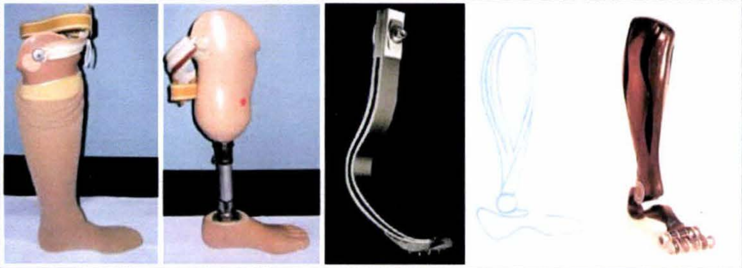
table 9

post trauma

reactionary phase

4.7

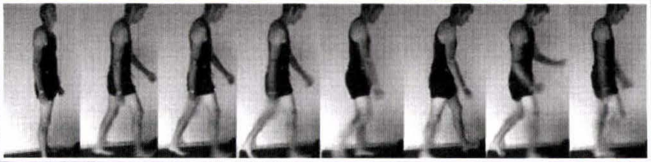
form



stimulus

stimuli interceptor recovery rehabilitation progression

interceptor



t

situation

function

rehabilitation

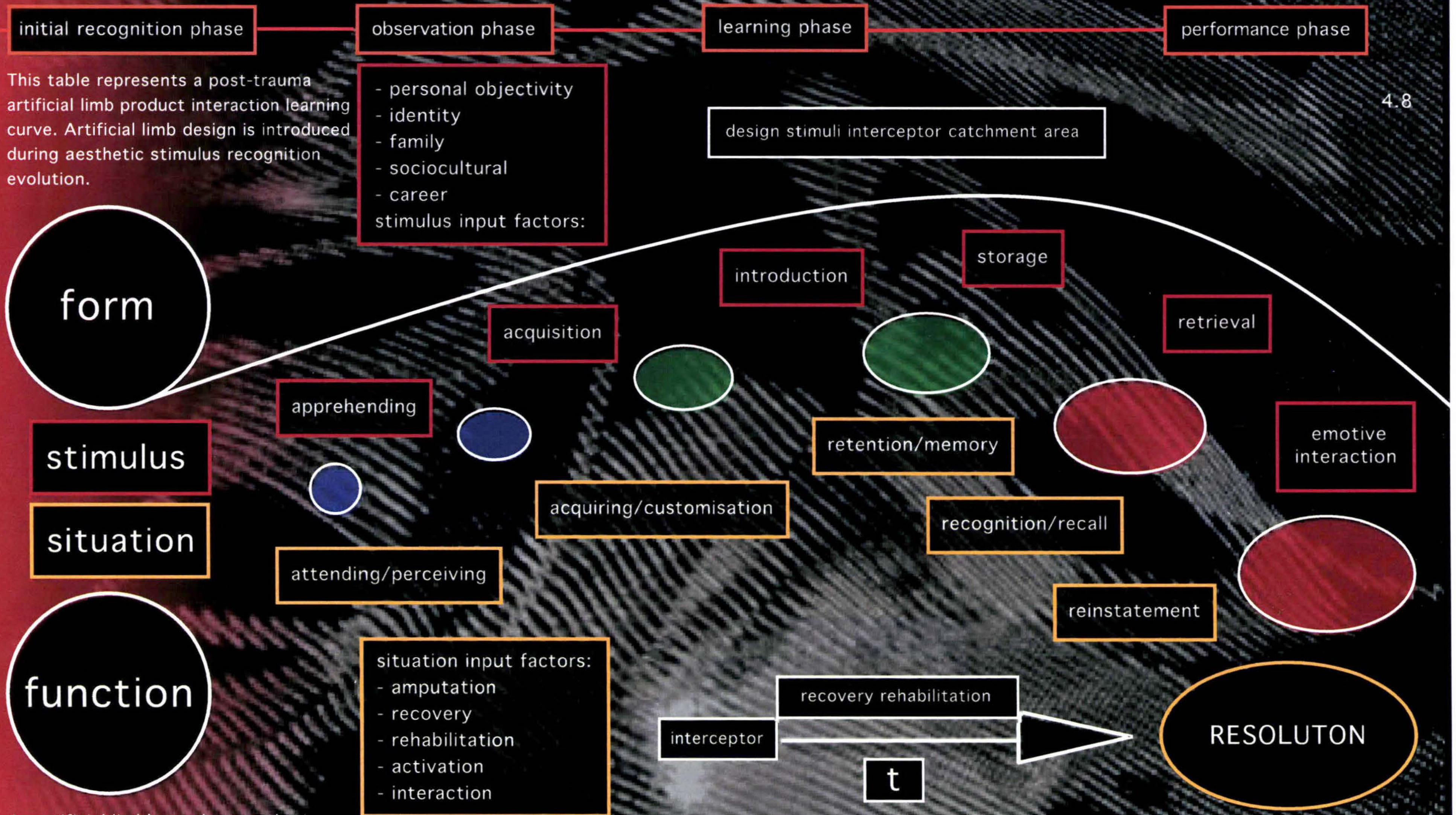
physiotherapy

restorative recovery

post operative conditioning

artificial limb product identification: pre-post trauma

This table represents a post-trauma artificial limb product interaction learning curve. Artificial limb design is introduced during aesthetic stimulus recognition evolution.



initial recognition phase

observation phase

learning phase

performance phase

- personal objectivity
- identity
- family
- sociocultural
- career

stimulus input factors:

design stimuli interceptor catchment area

form

stimulus

situation

function

apprehending

acquisition

introduction

storage

retrieval

retention/memory

emotive interaction

attending/perceiving

acquiring/customisation

recognition/recall

reinstatement

situation input factors:

- amputation
- recovery
- rehabilitation
- activation
- interaction

recovery rehabilitation

interceptor

t

RESOLUTON

An artificial limb's product aesthetic identification will evolve as the amputee's product situation evolves.

table 10

amputee/artificial limb: product event learning sequence

5.0

applied human aesthetic in artificial limb design
literature review

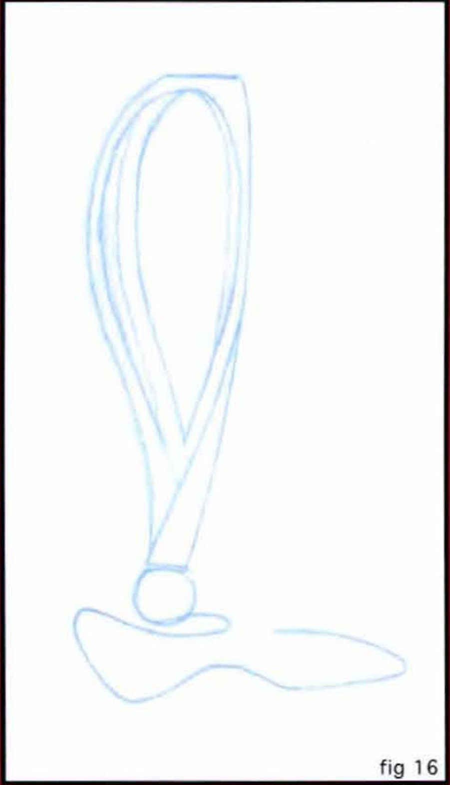
The following literature review incorporates a summary of relevant aesthetic theory, and combines this with product visual identification and its association with the artificial limb prosthesis. This literature review provides a point of departure for establishing an identifiable aesthetic value for artificial limbs. It also considers the design development methodology for this study in the context of the direction of the current artificial limb prosthetic industry.

'Aisthetikos' meaning perceptible by the senses.

'Is the residence of beauty in the object or the beholders mind?' (Voland, 2003, p.435). Human aesthetic is used in this thesis to mean appreciation of human body forms. Applied human aesthetic is the application of this to manufactured devices.

'Why do we find certain things beautiful?' (Voland, 2003, p.436). Voland suggests this question is popular to any student of aesthetics in his thesis, Evolutionary aesthetics. Why do we as humans have an aesthetic preference? One explanation lies in our evolutionary experience as defined by Darwin's framework where humans are able to make a 'spontaneous distinction between beauty and ugliness' Darwin (1858, cited in Williams, 2001). An evolutionary theory tells us that humans have an ability to adapt to changing circumstances and to make critical decisions in life. Chamberlain (2000), On the evolution of human aesthetic preferences, classifies three behaviours that define the characteristics of human aesthetic preferences:

- The symbolic behaviour humans have developed, for example burials, daily routine, ornamentation, and representational art.
- The evolution of human cognitive abilities, including the aesthetic dimension which contributes to developing human culture.



Natural visual geometrical symmetry, a spontaneous distinction between beauty and ugliness? This transtibial artificial limb modulus form is identified as an aesthetic replication vehicle.

- The cognitive responses to our emotional reactions to the appearance, or aesthetic of a structure.

Chamberlain summarises the term 'aesthetic' as 'mental appreciation of the shape or embellishment imposed on raw material'. The human aesthetic preference in which the 'appreciation' of art primarily denotes an involuntary emotional response to a stimulus, is a direct contrast to the 'deliberate intellectual stance' adopted by the social scientist. The term 'human aesthetic' (natural science) as a form is derived from evolutionary psychology; it is an adapted aesthetic preference resulting from an individual's identified preferences, and includes; their relationships with the human body, status symbols, social scenarios, and ideas. The aesthetic preferences of people today are the result of rapid and often unconscious responses to a range of stimuli.

Scruton (1998, cited in Williams, 2001) defines as 'animals, parts of the natural order, bound by laws which tie us to the material forces which govern everything'.

The human visual aesthetic preference has evolved from our individual responses to natural landscapes. Notable within this aesthetic is a preference for symmetry, identified in particular in relation to known environment or localised context. Chamberlain (2000) suggests the general properties of this process of landscape recognition are:

- the initial visual encounter;
- identification of features characteristic of the environment;
- deliberate design of artificial landscapes as exemplified by modern art and architecture;
- the visual landscape most strongly expressed by children;
- the surrounding environment in which an individual has grown up and adapted to, including intuitive preferences such as the surrounding topography, botany and fauna.

Geometrical symmetry is widespread in the natural environment and in human culture. The

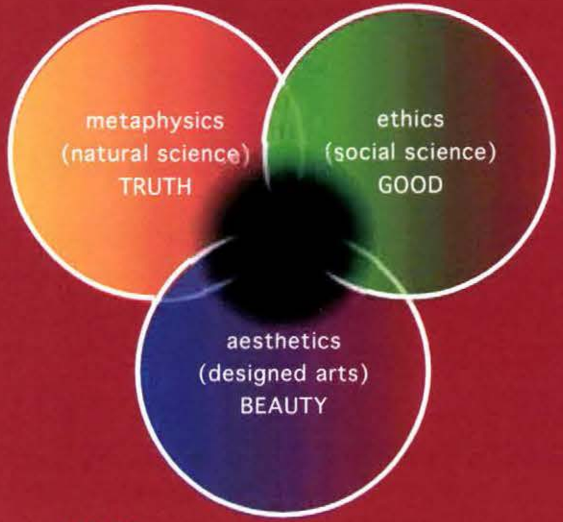


table 11

A creative semantic emotive stimuli to sensory reaction less defined parameters. The three branches of philosophy are shown here in lower case. The three fundamental human pursuits are shown here in capitals and the three corresponding fields of modern research and practice are shown here in brackets.

symmetry of form is often the dominant feature in relation to functional necessity. In other words organisms and artefacts often appear to be more symmetrical than is strictly necessary for the purposes of efficient mechanical design. Fashion often exhibits symmetrical patterns that are not dictated by functional considerations. An example is the external appearance of specific recognised features as a visual or tactile criteria in mate selection. Symmetry preferences may emerge as an unintentional by-product, a perceived measure of genetic quality. In humans these mechanisms for processing visual data from facial configurations are augmented by shared, possibly species specific, preferences in facial attractiveness.

'Whoever deals with aesthetics nowadays dissects a corpse' (Martin, 2004). Martin has established the aesthetic as a form of cultural identity. He suggests aesthetics has been maligned in 20th century literary theory, film and art history. He claims there are central dilemmas inherent in any aesthetic judgment, an example being 'determining the aesthetic as judgemental, multiculturalism'. This idea needs to be examined and certainly the traditional hierarchies of merit need to be challenged. Are our values objective and ethical? Do we currently have a postmodern tendency to devalue any form of critical judgment? Chomsky (1978, cited in Martin, 2004) describes 'A fluid conception of objectivity, as ideological holistic skepticism'. Martin suggests Chomsky, with his theory of human betterment, aims at an applicable model for a new version of objectivity, reorganising beautiful and good as the 'Post positive' realism, and he recognises that humans are shaped by idealism. Ones imagination is in part based on localised experience, 'the imagination provides the motive for all those symbolic stratagems by which a culture's wisdom or ignorance is refracted and transmitted' (Martin, 2004).

Aesthetic practice is never separated from the referential dimension of acknowledgement. The objective attitude that the aesthetic is never merely a function to be encountered objectively,

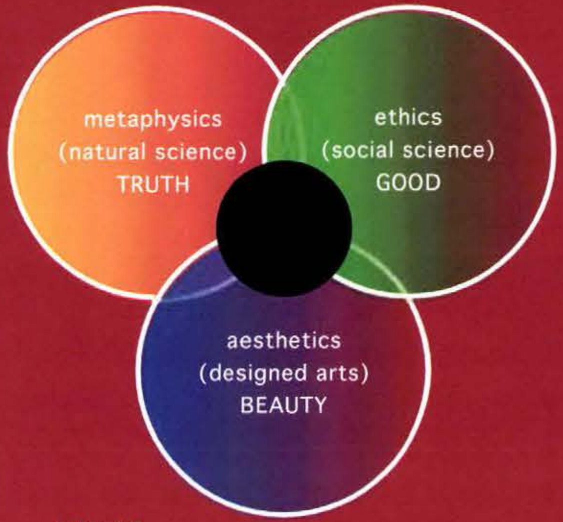


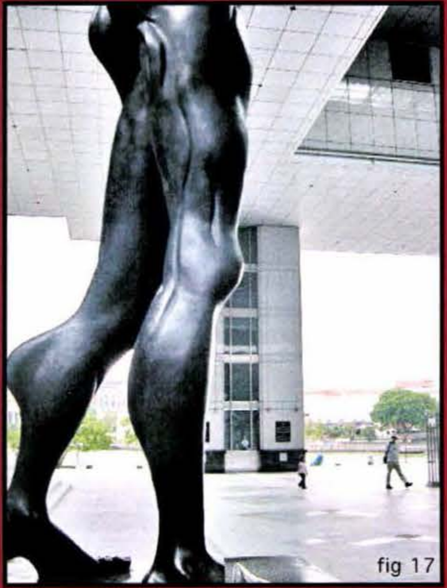
table 12

Theological semantic aesthetic, emotive idealogical perfectionism with clearly defined parameters.
The three branches of philosophy are shown here in lower case. The three fundamental human pursuits are shown here in capitals and the three corresponding fields of modern research and practice are shown here in brackets.

but is instead one of many functions that relays information to the imagination. We are subjectively identified as a cultural entity. 'Naturalistic evolution is incapable of adequately accounting for our aesthetic faculties'. (Williams, 2001).

In Aesthetic arguments for the existence of god (Williams, 2001), Williams claims that arguments in favour of aesthetics are 'traditionally subsumed under category of designed theory'. Aesthetic reality is a 'subjective awareness of beauty' and the objective being beautiful, an intrinsic aesthetic primary based upon our ability to know beauty. The nature of our subjective aesthetic to interpret this experience is personal aesthetic awareness. Williams claims that 'science does not deal with the value qualities of the aesthetic as moral' and that 'beauty as an aesthetic property is not a part of evolution theory'. The proposal that the experience of a god as the source and standard of object aesthetic value is expressed as follows, 'In experiencing beauty we feel ourselves to be in contact with a deeper reality than the everyday' (Williams, 2001). Williams states science does not deal with aesthetic value qualities in it's 'descriptions of the world' therefore beauty as an aesthetic property is not part of evolutional theroy. Darwin (1871, cited in Miller, 2001) maintains 'natural beauty arouses through competition to attract a sexual partner'.

Naturalism fails to account for the existence of human experience which includes 'the aesthetic experience'. Williams has used four categories to define aesthetic arguments and existence of God.
- Secular philosophers' aesthetic lends itself to religious treatment.
- Strong pull toward God when considering aesthetic phenomena, objectivity and meaning, fullness of beauty.
- Vitality of aesthetic creativity and appreciation.



Salvador Dali's Homage to Newton. Symbolic ornamentation. A cognitive response of an individual's interpretation to another's life long work.

- Natural environment for the appreciation and rational understanding of an aesthetic reality. Does the existence of a god, provide a source and a stantard of objective aesthetic value?

Art can seem revelatory or be seen to answer to objective standards; the aesthetic justification of experience. Aesthetic experience seems to produce the harmony between us and the world of that religion's resolution were it not all an illusion. Intellectually unsustainable aesthetic experience, however powerful, remains subjective despite the problems of alienation thrown up by science and morality. Great masterpieces of the past have imitated beauty, natural order, divinity that go way beyond the biological, interpreting the world as imbued with value and meaning. Ross (2003), states 'the erotic, both as representation and as response, can be classified as a separate aesthetic category', and defines this representation with a 'dual existence'. The intuitive value; that of pleasure in the response, and the natural feature; that of aesthetic presence.

'We must come at last to the clear knowledge that the human soul was made to enjoy some object that is never fully given in our present form of existence' (Williams, 2001). William's post modern society interpretation is the result of realisation that without the 'transcendent reference point provided by God the 'upper story' of value has become nothing but an incoherent miscellany of subjective relative opinions governed more by fashion than common sense'; the unintended products of material necessity with no objective value in truth, goodness or beauty. The argument to the validity of aesthetic experience is straight forward enough, only persons can mean things or impact meaning to things and so only through persons can art have any meaning.
'We are animals, parts of the natural order, bound by laws which tie us to the material forces which govern everything' (Williams, 2001).

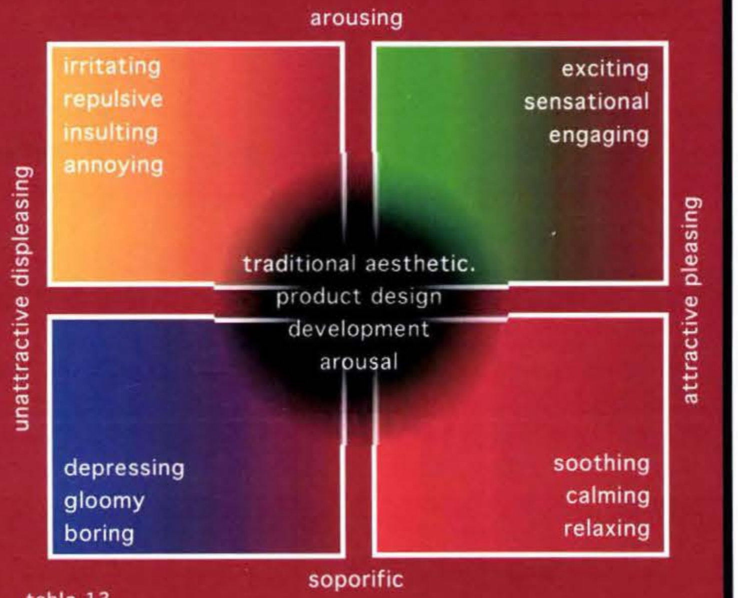


table 13

Aesthetic and arousal qualities associated with traditional approaches in product design development

Ruskin (1845, cited in Landow, 2004) asserts qualitative, universal judgments about the arts and has concluded the aesthetic is then used for purposes of naturalised institutional normative values, values that while unstated attempt to distance the art object from identity and cultural politics. How is a suggested interrelationship between the mind and an object best defined? Kaplan (1992, p.587) defines the interrelationship as an examination of 'technology' and its 'harmonisation on humanity, nature and society'. Kaplan (1992, p.589) emphasises 'evolutionary explanations of the human aesthetic preference benefit from integrated approaches that consider both cognitive and emotional responses'. Mono (1997, cited in Walter Parr, 2001), cites aesthetics as the 'study of the effect of physical gesalt (configuration) on human sensation'. He concludes that the product's communication or aesthetic channel, through product form and function supplies the user with a transmission or message. The receiver acknowledges, through product interaction, the product's aesthetic measage and will then establish an opinion.

'The functionalist intention is to express a bare minimun of what is needed, such as function and structure of the object in question' (Walter Parr, 2001). McDouagh, Bruseberg and Haslam state that there 'is a need to identify customer delights beyond functional values' (2002, p.232). Zafarmand in 'The relation of aesthetic and sustainability in product design' (2001), defines the aesthetic attributes of sustainable products as the most tangible aspect of sustainable development is that in which aspects of product and users are united in harmony. These attributes impact on users' spiritually resulting in intangible effects on product-user relationships. He defines the aesthetic (emotive) aspect of a product as an 'identification and character of a product, its image and form, visual and volume'. The form identifies the product character, aesthetically. This is a visual preference, as defined by symmetry. The result of this for the user is an emotional aspect of expression or 'real value' (Zafarmand, 2001). An effect of the aesthetic aspect of a product. Zafarmand defines the indentification and characteristic of product form. It is based

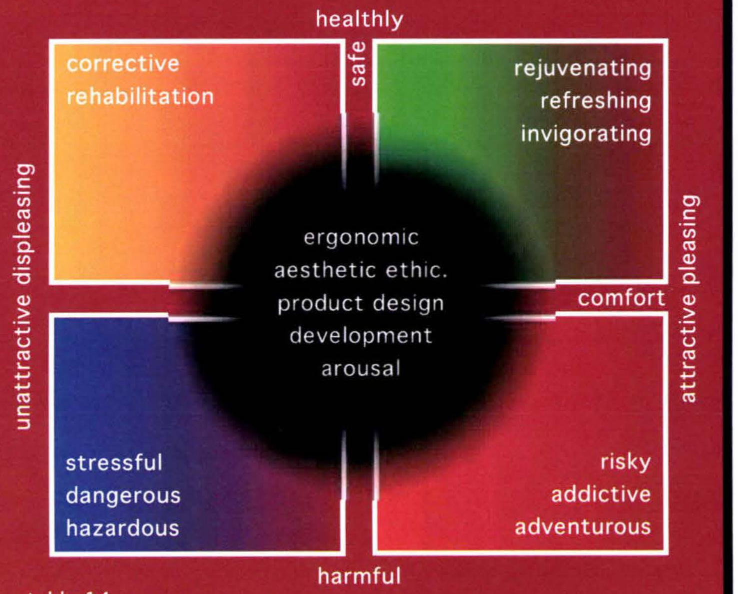


table 14

Aesthetic and psychosomatic qualities associated with product design ergo-aesthetic and ergo-ethic development

on the users; psychological and behavioural culture, and entrance into a social cultural structure, he classifies this as a 'real value' product aesthetic. The 'real value' attributes being characteristic of form, emotive aspect, fashion-ability, coordination with nature and environmental parameters, and sociological acceptability.

ergonomic aesthetic and ethic in product design

'Aesthetic judgement normally entails some attribution to the artist of intelligence, creativity, skill, maturity, imagination, conscientiousness, and agreeableness - or their oppsites' (Millar, 2001, p.23). The aesthetic and ethical dimensions of ergonomic human factors in design, explain how aesthetics and the human/machine interaction play a role in the success of the product. Designed aesthetics is not on the list of goals for human factors. While these human factors should be considered, ergonomic research is of great value for making ethical design decisions. 'The ethic of the ergonomic design in the designed aesthetic of product design should be considered the goal rather than the scientific study of the human/machine factors' (Yili, 2000).

Ergonomics is the science of designing for human use, 'the ability to design useful devices while making them even more usable' (Salvendy, 1997, p.438). This process becomes more valuable as the device becomes more complex. Ergonomic science is based on human physical and psychological performance. This principle predicts and evaluates the various aspects of human interaction and performance with the product, it's design, and the intended function. The incorporation of a product aesthetic and a design ethic in human factor design and development involves developing a 'theoretical and methodological scientific investigation of the aesthetic and ethic issues' (Yili, 2000). The measurement of a product's aesthetic and ethical value requires a comprehensive qualitative understanding of the product and its interfacing criteria. 'Identifying an individual's aesthetic and ethic design parameters through qualitative evaluation' (Yili, 2000).

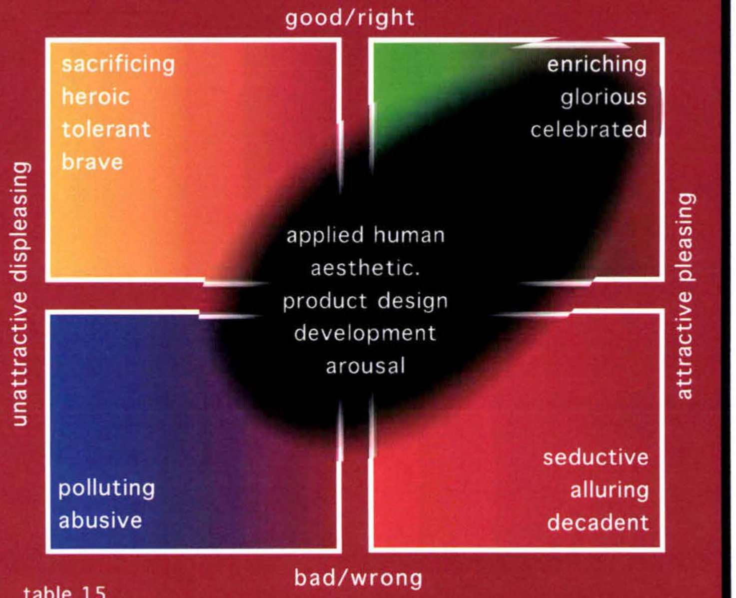


table 15

Aesthetic and ethic qualities associated with product research design and development direction in applied human aesthetic design development

'The functionalist intention is to express a bare minimun of what is needed, such as the function and structure of the object in queston. However history has shown that the nothingness of minimalism is in itself a powerful expression' (Walter Parr, 2001).

Yili (2000) states here the 'Ergo-Aesthetic' and the 'Ergo-Ethic' is a methodology that refers to the practice of making the designed product more ergonomically aesthetically responsible for its form, while maintaining an optinum functional ergonomic ethic. In addressing the aesthetic principle in product design and combining it with the ethical human machine interface environment, an 'ergonomic aesthetic ethic' is established. This addresses the functional interface through engineering and scientific evaluation, while incorporating the underlying needs and requirements of consumer 'real value' visual identity and self awareness. It is the responsibility of the designer to combinie these criteria to produce an applied designed product aesthetic.

[illegible] disability

Designing for disability requires sound ethical methodologies during the qualitative and quantitative research processes, product design development, prototyping and trialling stages. The aim of the designer when designing for disability, first and foremost, is to improve the quality of life for the individual. As Walter Parr (2001) suggests, 'let industrial products remind us of nature and the human body'.

Amputees as a subset of consumer society have long been disadvantaged when it comes to product design. Usability, appearance and even functional qualities have been sacrificed for the need to supply quantity in some cases. The daily social interaction of amputees is not hindered by their disability but by the lack of current designed product aesthetic and ethical criteria. The aesthetic dimension refers to an individual's aesthetic appraisal of a product's emotive stimulus, in this case an amputee's artificial limb, its use, task, and situation. The ethic dimension refers to the moral desirability or ethical acceptability of the artifical limb and or its action/interaction.

'Aesthetic judgement is a natural part of mate choice and social cognition, in which an art-work is viewed as the extended phenotype of the artist' (Millar, 2001, p.25).

Salvendy (1997, p.438) defines disability ergonomic research within three areas of study:
- The degree to which a task or situation or product usage arouses an amputee.
- Information processing demands or level of difficulty a task situation or product usage imposes on an amputee's information processing system; their perception, cognition, response, and task execution.
- Psychosomatic soundness; the degree to which a task situation or product usage contributes positively or negatively to the overall wellbeing of an amputee's mind and body.

The addition of both the above mentioned aesthetic and ethic dimensions applied to traditional disability research and development methodologies could significantly expand the scope of artificial limb product research design and development practice. The applied human aesthetic in artificial limb design deals with a qualitative input system from an identified target group, transtibial amputees, and their personal interaction with a targeted product group, in the case of this study, their transtibial artificial limbs. Table 15 explains the varying degrees of attractiveness and arousal an individual will experience with a defined product, and their relationship with its characteristics. 'This provides a unique experience measure of attractiveness and arousal levels for different users' (Yili, 2000).

The applied human aesthetic in artificial limb design should not imply restriction in design development to that which is pleasing or attractive, but merely advocate careful and directed selections in aesthetic levels of design while fulfilling the required functional needs and characteristics of the indented design or use. Evolutionary product development should consider the use of these reference markers as a foundation for point of departure in design development applications.

Disability design employs a high ethical content in product development. Attitudes towards the designing of products for a disabled community have progressed recently from the 'hand me down attitude' (Dillingham,1999), where an amputee's social status was that of an outcast. 'Positive reformed attitudes towards designing for the disabled are a product of socio-economic pressures from an older, wealthier sector of society' (Yili, 2000). This positive development suggests amputee demand (including that of war veterans) requires a certain human interface refinement in both form and function. Usability, comfort, aesthetic appeal and the natural functional attributes were factors that were initially considered secondary to that of the manufacturing process, quantity, supply, distribution, and possibly profit. This is changing as amputees become more aware of their needs.

Applied human aesthetic in artificial limb design requires the product's user to experience emotional qualities in a positive way with regard to his or her interaction with that product. An amputee's experience in interacting with the artificial limb should be both extremely pleasing visually and extremely positive functionally. Walter Parr (2001), states 'a product seldom gives the intended reactions, existing products might reflect the values of society or the user's creativity more than the designer's intentions'. The value of the applied human aesthetic methodology during the product research, design and developmental stages is reflected in this, whereas a lack of an applied human aesthetic in artificial limb design would cause emotional implications for the user within a society at a basic fundamental level.

A suggestion that the human aesthetic 'experience' can be reduced to a scientific explanation (function) without discussion of the relation to 'meaning' in which we attach an experience and/or our 'interpretation' of that experience (form), defines a basic conflict of philosophical design understanding. 'The awe of expertise that is induced by social institutions as one device for imposing passivity and obedience' (Chomsky, 1978).

The applied human aesthetic in artificial limb design does not need to rely so much on explanation but should aim more towards a harmonised balance with perception. Design development exploration through 'the public language of appearance' (Darwin, 1858).

5.1

salvador dali
homage to newton

Salvadar Dali (1985, cited in Knight, 2002) paid homage to Issac Newton, the self-made genius in his bronze statue 'Homage to Newton'. Homage to Newton has many interpretations from unknown sources;
'A post humorous reputation, riddled with contradictions'.
'Disturbingly empty oval instead of a face allowing us to impose self interpretations of a man, from which the central core of the man himself is missing'.

Salvadar Dali's personal flavour of surrealism influences interpretation and social surroundings. Dali's work is based on his own personally-inspired system or methodology he called the 'Paranoiac Critical' method, whereby 'A spontaneous method of irrational knowledge based on the interpretative critical association of delirious phenomena'. This method was explaned by Dali in the first issue of Le Surrealisme au Service de la Revolution (1930). This method was considered an extension of Dali's own fevered mind and personality. As Dali (1934 cited in Knight, 2002) said himself 'The only difference between me and a mad man is that I am not mad'. The Homage to Newton by Salvador Dali is the representation of Newton's Law of gravity. The origin of the most fundamental law of physics can be seen in the falling apple, the ball falling from the right hand. Characteristics in this work such as, the opening of the torso on the figure and suspending the heart indicates that of an open heartedness (fig 19/20); the opening of the head representing an open mind; two suggested qualities required in an individual discovering the natural laws of physics. The form of the right leg on the figure (fig 18) represents a physical 'godliness' or an applied human aesthetic, which is both whole and pure. It is worshipping on Dali's behalf, the basic physical principles of natural form and function. The varying shape of the figure and form depends on the angle and approach from which it is viewed.

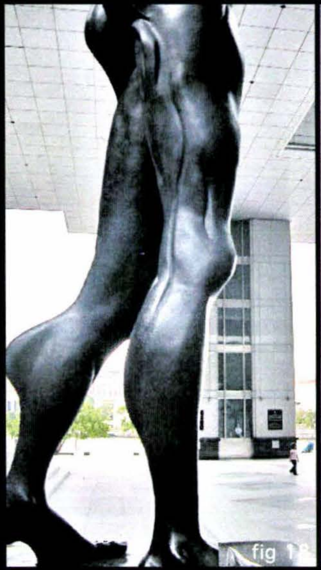


fig 18


fig 19


fig 20

5.2

a gothic style
product culture and architecture


fig 21


fig 22

Ruskin (1845, cited in Landow, 2004) states 'Man can not advance in the invention of beauty without directly imitating natural form'. The 'gothic' style provides an excellent example of exo-skeletal architecture, and has produced a variety of unique and culturally distinctive products with a strong identity. The gothic style derives from the mystic and deformed, yet gothic influences in exo-skeletal form and structure can be readily found in modern day product design. Most science fiction movies will have a gothic-styled derivative in either the set design or its associated products. So what is it about the gothic form that should gather so much attention?

The point of interest with the gothic style is both in the structural details and the overall emotive quality. It is especially in this unique and stylised detailing that the true gothic style is seen, recognised and distinguished. The tradition of creating a piece of work that is entirely gothic in style and culture is referred to as the whole or total piece of work, with the process referred to as GESANTKINWERK.

Two distinct characteristics of the gothic style are the impression it receives from human empowerment and the image it bears of natural creation. This unique visual style resembles a spiritually heightened functional state of existence. The final aesthetic product is justified as being spiritually beautiful, godlike, perfect and also seductive, while still retaining the mystic qualities of the unknown.

In the legendary rock group Kiss, Genne Simmons (fig 25) has created an impression of power but is a distorted version of natural creation. It is in this distortion that the group's unique image is forged. The point of departure for Kiss has been the band's product design and image, which uses Gothic style as a metaphor for the unnatural distortion of beauty and the corresponding


fig 23

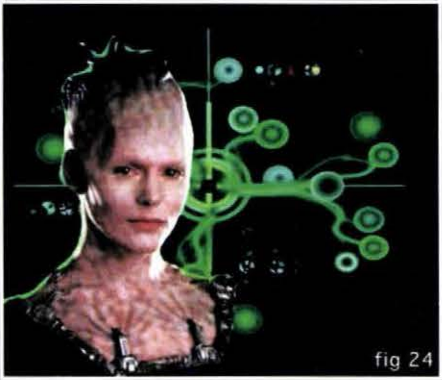


fig 24

underlying meanings. Defined by their distinctive sound and theatrical performances Kiss and its followers, have created a sub culture that has played on the unknown qualities of evil and the grotesque, questioning evil's prevalence. Is it to be worshipped or feared?

In George Lucas's movie, Star Wars Episode 2, Attack of the clones (2002), we were introduced to an amphitheatre of death, Geonosis (fig 22). This circus-like arena is riddled with gothic metaphors in both the design and the characters that inhabit it. The architecture is derived from the naturally deformed, yet it supplies the gothic-inspired flying buttress as a visual reference. The characters are gargoyle-like in appearence and revel in the pain of others.

The 1996 movie Star Trek First Contact the Borg Queen can be seen to employ an interface attachment system that integrates the physical with the machine. The ideal of replacing limbs and other selected pieces of anatomy to enhance the basic functional attributes of bi-pedal actions is both intriguing and grotesque. This system includes an embedded chip paired with sophisticated sensors. It has established a new generation of components to replicate with increasing fidelity the complex functions of a normal body part. This system also involves 'biometamorphic' adaption in which the machine replicates the humans body's natural function. The form then becomes that of an after-thought, as seen in their grotesquely manipulated form of a cyborg (figs 23/24).

In Charles Darwin's Origin of species (1858), Darwin claimed that 'man was not made after the modelling of the god's shape, but evolved out of an ancestor who resembled a monkey' (1858, p**). This theory, sensational at the time, created serious religious and ethical controversy and brought about a revolution in the field of science by providing a detailed and systematic explanation of 'natural selection'. This evolutionary theory has dominated the science of the human race and still creates controversy among creationists today.

What of an evolutional process that considers the combination of both the natural and the machine? Ridely Scott's 1986 movie Aliens plays a very interesting role in its portrayal of the gothic style as pure evil. H.R. Giger designed the beast for this movie, and in doing so created a new gothic styled genre associated with fear (fig 25). The Alien or beast incorporates not only the unnatural, unearthly, visually grotesque gothic style but it has been defined with an exo-skeletal product reference, the creature's form.

In Matthew Barney's 2003 movie The Order-Cremaster 3, Amiee Mullins, a bi-laterial transtibial amputee athlete, appears wearing crystal/glass artificial legs and high heal shoes (fig 26). Here is an example of an artificial limb's visual beauty and grotesqueness. The replaced natural form of her leg in high heel shoes made from cyrstal/glass is stunningly beautiful. The attachment of this aesthetically cold inhuman product to a human, is grotesque.

Bladerunner, Ridely Scott's 1982 sci-fi epic based on Philip K Dick's Do Androids Dream of Electric Sheep, introduced a cyborg character that was considered superior to humans in both intelligence and strength. Called Nexis-class replicants (fig 27) they were designed to work [as off world labour] in harsh environments. While evolving emotional responses, memories and personal identities they were confined to a four-year life-span. This bio-metamorphic machine aesthetic is hidden inside a natural, 'beautiful', 'god like', or perfect shell resembling the human form. While not visually grotesque, is the grotesque in metaphor that of visual perfection replication, human charactristics and/or GESANTKINWERK?

The continuing influence of the gothic style on modern day product design poses the question, are we to remain completely human, or is the machine and its functional reliability to be our future?

5.3

state of art
structural expressionism

'Strength, toughness, stiffness and flexibility are essential for the existence and continuity of all forms of life' (Gorden, 1998, p23).

These laws have applied to both natural and man-made objects through the ages. The mechanical properties of materials applied to any structure are the foundation for a successful design process. The functional property attributes combined with the applied material form will result in both a unique and enhanced design platform.

Biomechanics is the study and behaviour of living materials and structure. From the study of biomechanics basic design principles can be formulated to direct and advance the design process. The unique attributes of specific man-made materials can be utilised to enhance the aesthetic that visually identifies an individual style. Structural expressionism is an architectural example of these methods.

Structural expressionism is also referred to as 'High Tech Modernism'. This specific style or branch of advanced architectural modernism can be seen when a building's structural support is positioned on the exterior thus integrating it as part of the design aesthetic (figs 29-30). The larger designed features on display reveal the structure as a load-bearing entity. The impression of an over engineered structure is a unique and identifiable style that is a result of, for example, the unique structural supports of a large bridge. Common themes of this style are detached external framing, exposed truss work, varied exposed material interactions and highly complex shapes that require unusual and

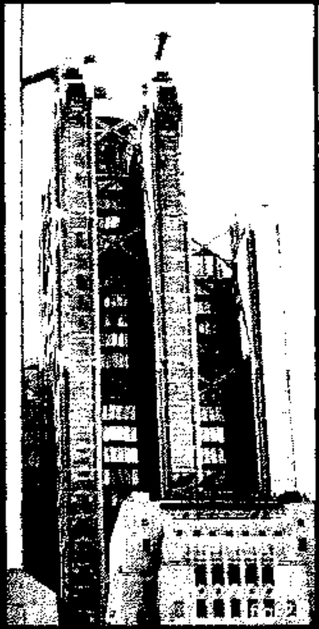


fig 2

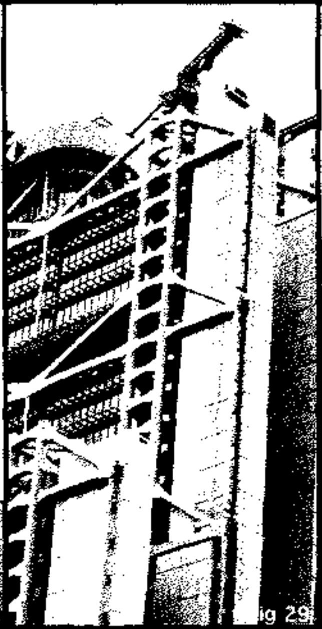

ig 29


fig 30

sometimes extremely complex engineering. All of these facets are aimed towards the designed visual impact, the load bearing capabilities of the structure and, most importantly, the initial concept objective, to house people safely and efficiently.

Structures designed and built in this style usually involve construction materials that reflect their own unique capabilities. Metals, glass and composite concretes are all materials that identify this style. An example is the Hong Kong Shanghai Bank designed by Foster and Partners, one of the world's leading architectural practitioners. Commonly referred to as 'the bank', the Hong Kong Shanghai Bank is considered one of the world's most famous skyscrapers. This 179m tall building includes a 10-story high glass atrium that looks out over the harbour (fig 31). It is considered one of Foster and Partner's most famous architectural designs and has established itself as a Hong Kong icon. Foster and Partner's philosophy has always been guided by a belief that the quality of our surroundings has a direct influence on the quality of our lives, whether it be in the work place, at home or in the public realm.They also state that their designs acknowledge that architecture is generated by people's material and spiritual needs, a concern for the physical context, and a sensitivity to the culture and climate of a place.

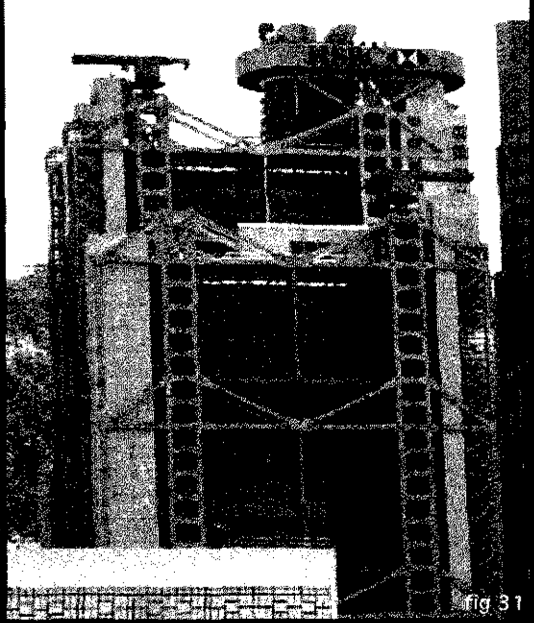


fig 31

5.4

the machine aesthetic engineered culture or functional criteria?

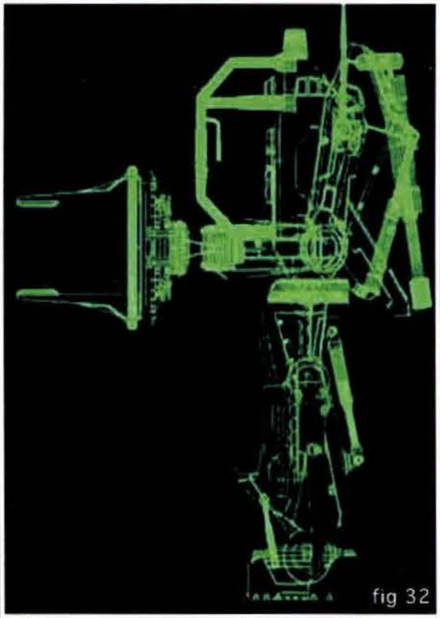


fig 32

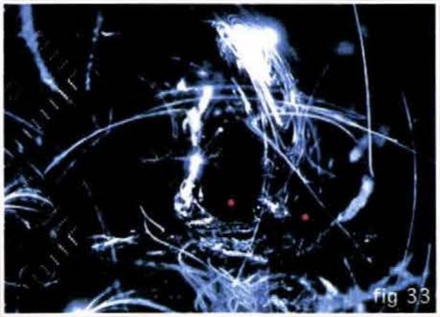


fig 33

The University of Tsukubu in Japan, claims to have an 'evolvable hardware' processor CPU that is able to redesign itself to process signals from an individual in the most efficient way yet possible. This CPU is considered to be the start of a new generation of evolving software systems. Connections between its reconfigurable logic gate are determined by a sequence of data that can be changed at will. The chip evolves new sequences in the same way living creatures evolve, using genetic algorithm. The sequence of data that describes logic arrays can be treated like genetic information and different sequences are continued or mutated to breed new offspring. The evolving learning software process consists of: [evaluation = optimum performance criterion + performance criterion = mutation]

The last 25 years has spawned many advances in prosthetic limb technology. The integration of lightweight materials and electronic mechanisms are providing new and exciting development opportunities. Advanced prosthetic devices are integrating computer technology with high composite materials, movements of artificial limbs are controlled by software and actioned by hydraulic and pneumatic materials. The ability to mimic natural bi-pedal movement with the help of high powered portable computers that are internet-capable will progress the design of the semi-robotic artificial limb into the next generation, tackling not only basic tasks such as climbing stairs or treading on uneven ground, but also catering to sporting activities and other physical challenges (fig 32).

What makes a human superior to a machine? As McDouagh, Bruseberg and Haslam (2002, p.232) point out the emotional relationship between the user and product is determined, to a large extent, by the symbolic dimension of the product. The symbolic meaning of an object often relies on shared understanding between individuals. Is it in the way we are able to think creatively or act illogically? Is it in the way we look and identify?

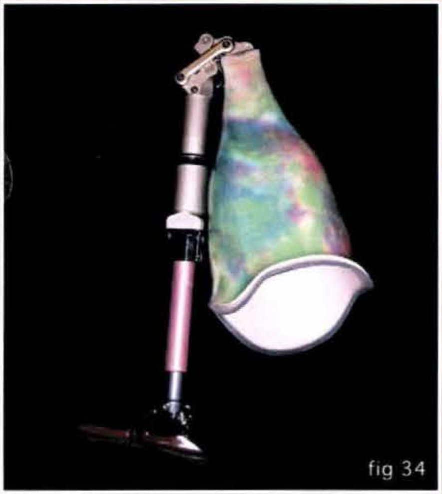


fig 34

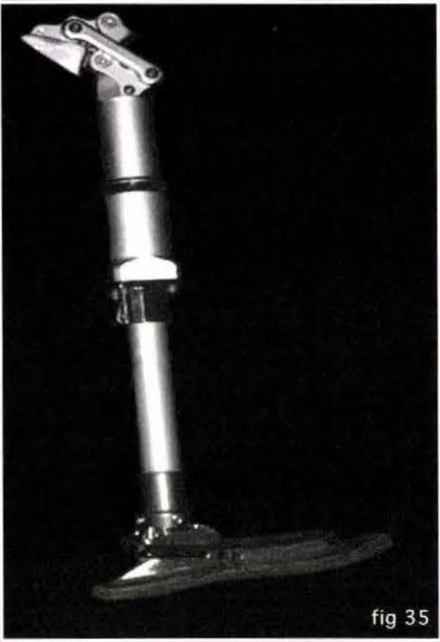


fig 35

Harraway (1999, p.150) states that the 'The cyborg is a condensed image of both imagination and material reality, the two joined centres structuring any possibility of historical transformation'. Amputees and biomechanics have fundamentally different views about what contributes to an ideal artificial limb and the relative emphasis on function or form. This difference suggests that biomechanics locate and manipulate technology and materials to produce a satisfying functional result. In doing this a machined aesthetic is created to work cohesively with the functional dynamic objectives. The biomechanics objective ideal being the refinement of the products' functional aim, to operate as naturally as possible with its user. Many new amputees identify the artificial limb's objective ideal as the object as a whole or a product representation (figs 34-35).

Is a prosthetic device efficiency determined by the user's ability to undertake physical activities such as running without considering the missing humanistic aesthetic?
Is the user's ability to run dependent on the artificial limb itself rather than the relationship between the amputee and the artificial limb?

'A new class of digitally controlled self adopting smart legs that offer much more freedom, strength and balance' (Seyfarth, Geyer,& Herr, 2000, p.295). The basic question one now must ask in the artificial limb research and development process is how this human machine relationship affects human bodies and subjectivity. The prosthesis acts upon and determines the body's movement by reconstructing it, propping it up and revealing it as artifice (fig 35). It is an integrated component in the human/machine relationship. Does the technology then threaten to violate the amputee's identity or sexuality? Haraway claims 'the cyborg is a creature in a post-gender world; it has no truck with bisexuality' (1999, p.150).

fig 36

Prosthetic design will ultimately enable us to transcend the limitations of our bodies, whether this is advantageous or threatening to the users, the interaction of this relationship is a direct one in which the prosthesis has agency to determine the body's functional performance.

This type of exo-skeleton product is a protective robotic outer shell that enables increased physical performance in a person's physical abilities. The United States military has looked into developing exo-skeletons for military purposes. The Defence Advanced Research Project Agency (DARPA) considers that exo-skeleton technology, has potential to give soldiers critical advantage during warfare as well as helping civilians, disabled people, construction workers and rescue workers responding to fires and natural disasters. Heinlien (1959 as cited in Weiss, 2001) states 'The beauty of a powered suit is that you don't have to think about it. You don't have to con it, operate it, drive it, fly it, you just wear it and it takes orders from your muscles'.

In the 1960s General Electric's research and development centre in Schenectady, New York designed and built a self standing hydraulic powered exo-skeleton named Handiman 1 (fig 36). It was as heavy as a car while enabling a person to lift a fridge like a bag of potatoes. It's drawback was Handiman 1 could only ever function with one arm at a time. Attempts to operate both legs at the same time would lead to a violent and uncontrollable motion.

The most notable example of an exo-skeleton is the power loader off Ridely Scott's 1986 movie Aliens. The human machine interaction and interface system is not unlike current prosthetic devices; the all encompassing interface system that immerses the user. There is a clear train of thought amongst engineers regarding a machine's functional attributes and that of its aesthetic interface qualities; maximum functional performance takes priority.

The human machine interface, an established important criteria for machine human productivity is still relegated as an afterthought. This extremely important interface aesthetic is still currently machined by engineers when it should be humanised by designers. This is where the interface interaction productivity limitations will always fall flat until this train of thought is changed.

mark inglis's custom designed [illegible]

Mark Inglis is a uni-laterial transtibial amputee.

In 1982 while working in Mount Cook National Park as a search and rescue mountaineer Inglis lost both of his lower legs to frost bite while trapped on the side of Mount Cook during a climb to the summit. Dug into an ice cave with fellow climber Philip Doole at over 2500 meters for 13 days took its toll on Inglis and forever changed his life. Both men lost their legs during that formidable storm. After Inglis had recovered from the amputation he was 'challenged to rethink his life' (Inglis, 2002, p.37). In doing so he decided to attend Lincoln University where he studied for a Bachelor of Science in Biochemistry. After joining Montana Wines as a Senior Winemaker Inglis took up sport again. He has now competed nationally and internationally in disabled alpine skiing winning gold, silver and bronze medals as well as being in the New Zealand Disabled Road Cycling Team where he has competed at World Championship level and at the 2000 Sydney Paralympics in the 1000 metre individual time trial. In 2002 Mark finally reached one of his long term goals, climbing to the top of Mount Cook.


fig 37


fig 38

Inglis's transtibial artificial legs were designed by Wayne Alexander from the famed Britten Design Motorcycle Team with the help of the New Zealand Limb Board. Made from titanium and other composite materials such as carbon fibre Inglis claims to have 'put them through their paces' (personal communication, May 3, 2004). With an expedition to Everest planned in 2006 Mark seems to push the envelope in adventures. As a result of his constant training, he recently put a hole in the back of one of his residual limbs thus putting a stand-still to some of his planned activities. Inglis uses different types of transtibial artificial limbs for his various activites (figs 37/38). He has a special pair specifically for riding his mountain and road bikes. These limbs consist of twin carbon fins running the vertical length of stump. Being such an active individual, Inglis suffers from skin ulcerations on his residual limbs due to the constant rubbing of the socket liner against his stumps. Inglis has said 'sometimes there's a bit of anxiousness as to how much it's going to hurt for the first half hour' (personal communication, May 3, 2004). Having access to a range of custom prostheses does help him pursue all of his interests.

The Britten legs that were used to climb Mount Cook did not come cheaply. There was extensive testing of prototypes, some of which were not so successful according to Wayne Alexander (ex Britten Motorcycles). Even the formidable Britten artificial limbs use a basic socket system. Wayne claims that the socket system is the 'most reliable to date, while there are advances with fusing magnesium and titianum to bone we had to opt for something that would not directly affect Mark's performance or his ability to simply walk' (personal communication, Sept 10, 2003).

'If you have a sore leg for a whole week you are not a very nice person' (Inglis, 2002, p.86).

fig 39

fig 40

fig 41

The idea of someone forgetting that they are missing their legs shows an incredible will to live and enjoy life to the full. Inglis does not let obstacles stand in his way, he seems to be the kind of person who goes after the things that are important to him and which he is passionate about. Inglis claims that 'there are issues to be solved' (personal communication, May 3, 2004) regarding attachment of his limb (figs 39-41). In late May 2006, Inglis reached the summit of Mount Everest.

6.1

transtibial prosthesis
artificial limb product review

introduction

The transtibial (below knee) prosthesis is an artificial limb device designed for residual limb amputations across the tibial and fibula bones below the knee joint.

Traditionally this type of prosthesis is divided into two sections:

a) transtibial short prothesis;

b) transtibial conventional prosthesis, containing short prosthesis, and thigh sleeve.

The latter model has now lost ground to the short prosthesis due to advances in design development and manufacturing techniques regarding residual limb (stump) encasement, or sockets.

Advantages of the short transtibial prosthesis are: less constriction and antrophy on the localised muscle groups in the upper leg and less limitation of natural knee movement and stride. It is important that the residual limb fits to the capturing socket correctly. The direct interface between socket and limb provides primary product control and initiates user ability factors. Product interaction, comfort factors and other requirements of an amputee are all vital components when using an artificial limb.


fig 42

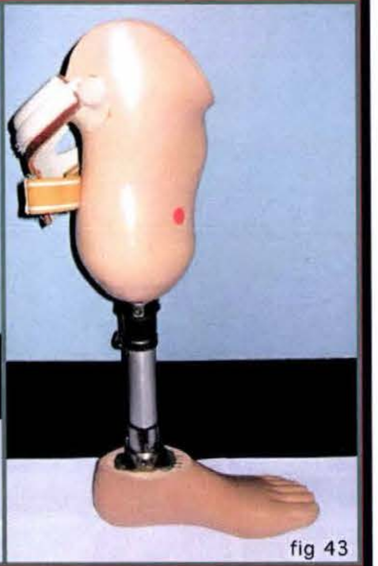


fig 43

The transtibial prosthesis is currently constructed as either modular components (fig 43), or as an exo-skeletal design glass fabric lamination, producing an exo shell (fig 42).

The adjustment capabilties of the modular system allows precise adjustments, made during trial fitting of the prosthetic alignment. The exo-lamination technique is applied after the trial walking phase is completed.

Other options for this prosthesis are often customised to meet an individual's needs. A transtibial residual limb plaster negative can be produced under vertical load to gain a biomechanical alignment measure of the total surface area and volume of a limb. The success of this artificial limb's direct control system depends on how perfect a fit the socket is. Although there is very limited soft tissue surface area available with a transtibial residual limb, a prosthestist can accomodate an individual's needs by using layering application techniques such as silicone liners and gel polyurethane liners. The gel liners are common with individuals whose residual limbs are sensitive due to scarring and/or low soft tissue volume.

The visual aesthetic of these transtibial artificial limb examples is very basic. The modulus machine aesthetic of the artificial limb in (figs 43/44) is clearly identified. The exo-skeletal artificial limb (figs 42/45/46) while undertaking a basic natural generic form, fails dramatically in achieveing any sort of individualised emotive aesthetic qualities. Both of these artificial limbs do not supply visually any form of product quality.


fig 44


fig 45


fig 46

6.2

state of art
product review

The importance of sporting activities for the disabled, and their influence in amputee recovery and prosthetic technical advances can not be underestimated. Disabled sporting achievements are now commonly-acknowledged worldwide, and the development of prosthetic equipment for high-end activities can only have helped the overall evolution in prosthetic limbs.
During the research and development phase of extreme prosthetic limb usage, a new set of design criteria, including new types of material research and development has evolved.

The C Sprint (figs 47/48), otherwise known as a bow leg or kangaroo tail (depending on the brand of product), is a tibial sectioned carbon fibre laminate that is specially designed to allow maximum dymanic energy return behaviour. While it is established that the behaviour and comfort of an artificial limb is of great importance to the user, during a normal walking cycle, during a sprint or run the behavioural factors or design criteria of the C-Sprint are greatly enhanced. The special movements of the amputee during high-level activities, require both precise and even distribution of focused forces and returned energy to maximise efficiency.

The large double bow shaped carbon spring is designed to create a long spring excursion for engergy return of the C-Sprint during sprinting (fig 48). The underside is spiked with rubber cushioning.

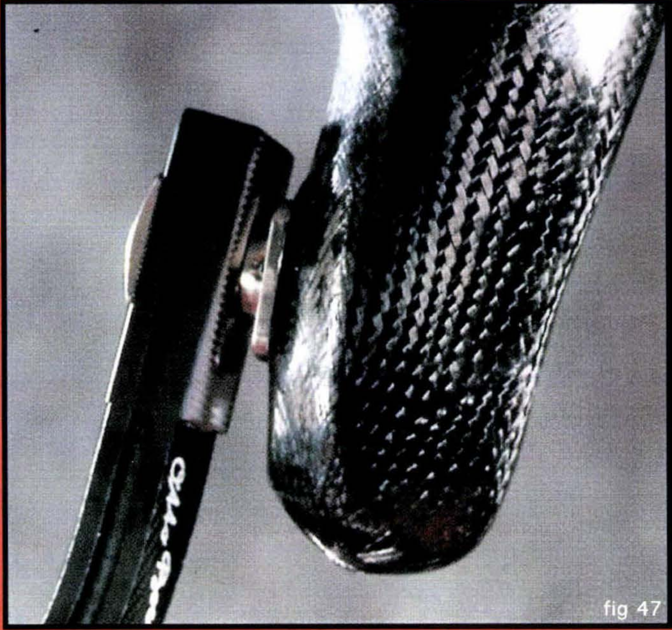


fig 47

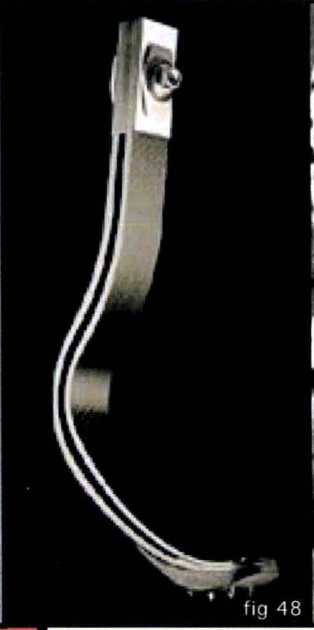


fig 48

fig 49

The C-Sprint prosthetic socket and modular adaptor allows for height and angle adjustments of the double spring, depending on the user's requirements.

The visual component of this product is exciting. Its form is visually the opposite of the natural shape one expects to see. While there is a suggested visual machine aesthetic, due to its high-end functional requirements, this product's form stands well removed from the natural form of a transtibial sectioned limb. At this level of participant activity, the C-Sprint would only ever be worn for smaller periods of time and certainly not used as an everyday prosthetic limb (figs 50/51).


fig 50


fig 51


fig 52

state of art
product review

fig 53

The ToeOFF orthotic lower leg foot support (fig 51) is designed to minimise the effect from ankle instability causing footdrop. The cause of the symptom footdrop is most commonly a side effect of a stroke, multiple sclerosis, polio, or spinal cord injury. Other neuromusclar deficits can also cause this effect. The aim of the ToeOFF orthotic product is to allow individuals with orthotic anomalies to be able to walk much greater distances than they would be able to under normal conditions. The reinforcement of a normal gait pattern is required by a patient who wishes to be able to self-propel his/herself during the gait cycle or stepping phase of walking.

The biomechanical role of the ToeOFF relates to the push-off the user requires when dynamically unloading kinetically stored energy. The open heel design allows for the natural enversion and inversion movement of the heel as well as reducing stress on the proximal joints of the ankle. The anterior plate (shin area) assists with the knee extension at the mid-stance phase of gait. The ToeOFF is designed and built using carbon kelvar lamination fabrics. The ability of these materials to form a predetermined naturally fitting organic shape, provide strength and comfort while maintaining a lightweight exo-shell is essential to the performance of these products.

The suggested benefits of the ToeOFF are:
- Gait improvements, provide a more natural and dymanic gait with less stress on other joints.
- Stability, the orthosis follows the lateral contours of the lower leg and ankle for greater support.
- A customised, personally-shaped fit to meet individual needs.
- A lightweight product, eliminating muscle strain.
- A thin, exo-shell which allows for use with normal footwear.

The ToeOFF is an exo-skeleton based product with an applied human visual aesthetic, designed to be able to use the characteristic properties of the material it is made from, to achieve its product aims and objectives.

state of art
product review

otto bock c leg

The Otto Bock C Leg is the world's first microprocesser controlled hydraulic knee with swing phase control.

The C Leg (fig 54) is a monocentric knee joint, designed and engineered to act as a natural knee joint for transfemoral (above knee) amputees. With this unique prosthesis an amputee does not need to swing the residual limb (stump) forward to produce a swing phase kick as would occur with a mechanical hydraulic knee joint. The C Leg automatically detects the static and dynamic swing phase of an amputee when walking. To initiate the forward swing motion of an artificial limb sensors built into the C Leg read and then adapt to the user's every move. A microprocessor interfaces with software loaded onto a personal computer. Adjustments can then be made to tailor the C leg to the amputee. The movement of an individual is then recorded and measured at 50 times per second. Dynamic gait can now be monitored, the end result allowing the user seamless access to various terrains otherwise impossible to tackle with a tradional knee joint. This method of product fine-tuning is state of art within the prosthetic industry and is aimed at the high-end market.

The C Leg is designed, engineered and produced according to a strict set of design criteria that are stringently followed. The production process for the C Leg requires the calibration of very delicate technology. The outer covering (fig 55) of this product must therefore provide protection for internal components and from the various external environments and forces encountered.

fig 54

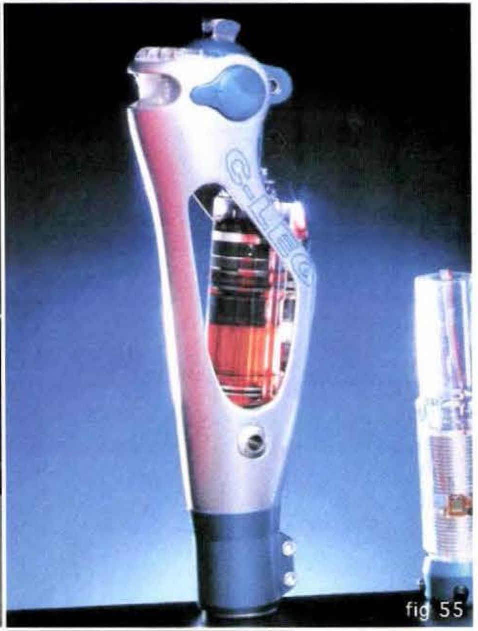


fig 55

exo skeletal architecture

The outer structure shell of the C Leg unit is an example of exo-skeletal architecture (fig 55). It is constructed from carbon fibre and provides supporting structure through a direct connection to the upper joint section or femoral shank and residual socket. The carbon fibre exo framework includes a battery, processor unit, tibial and femoral shank clamps, hydraulics and servo motors.

The carbon fibre exo skeletal structure of the C Leg is responsible for housing its functional attributes and it is also directly involved in the product's form, and identity. All aesthetic criteria derive from the final form of the product. Currently the shape and volume of the C Leg's packaging suggests (figs 56/57) an intention to provide a protective covering to house the functional contents structurally with a unique identity. There appears to have been little effort put into the shape of the product replicating the equivalent tibial secton of a natural limb. Arguably the reasoning behind this is that the parts make up the sum, hence form follows function.

The later introduction of a rain-resistant poly-carbonate outer shell or covering accessorised the C Leg (fig 56). The design criteria indicate water resistance and load-bearing directed through the kneeling position. The clear window identifies a visual interest in the componentry. The outer shell's form and shape is detailed by product identity and the functional components it is covering (fig 58), rather than the natural limb it is replacing.

fig 56

fig 57

fig 58

6.5

state of art product review

kuka robotic arms

The Kuka philosophy is based in 'creativity, dynamism and innovation'. It has been shaped by an understanding that man-machine challenges in the future will be determined by design developments today, that precise customer requirements are a necessity in product design, and a recognition that product innovation involves equally product form and function (figs 59-61).

Due to the world wide increase in demand, robotics is fast becoming the core element in the automation industry. As industry growth directs refinement in functional observation, output and demands, new areas of application 'around and beyond' the traditional automotive industry has grown. The current range of Kuka automated robots consists of a direct drive hydraulic arm with up to six degrees of variable movement. Robotic abilities today go well beyond the traditionally conceived 3 dimensional movements of the past. Various tasks are now possible and include, for example, tightening a screw, painting, welding, wrapping up and packaging items. Kuka robotics are now designed for more efficient and productive results than conventional systems.

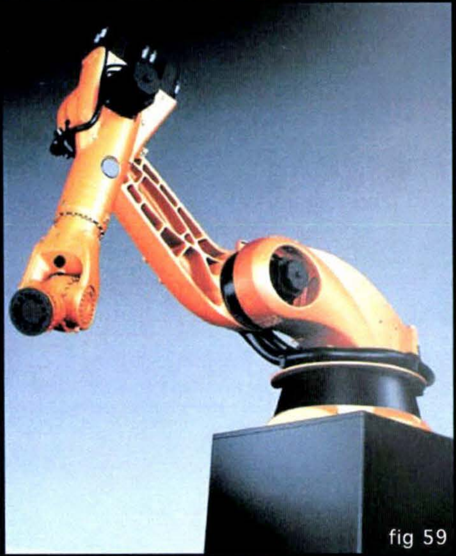


fig 59


fig 60

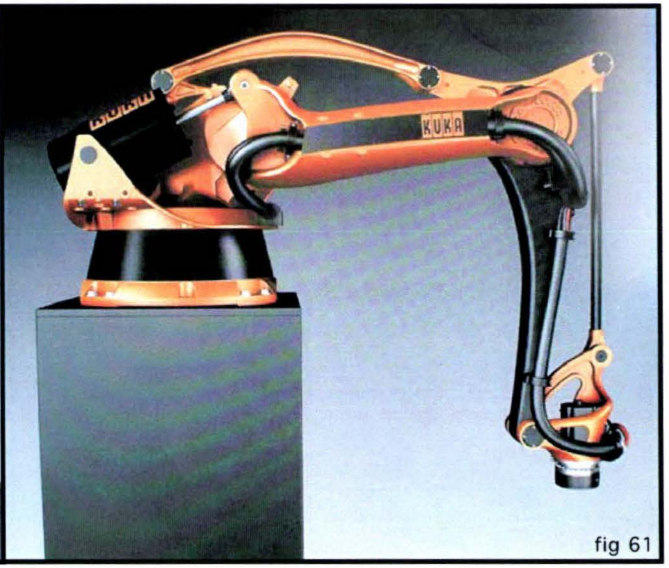


fig 61

Another important consideration for Kuka is the evolution of man-machine interaction technology. For example, safety standards have been developed to ensure human machine cooperation on the factory floor.

Examples of these processes are:

a) the combination of human and robotic uses in the entertainment industry.

b) the use of robotic services in the automation industry with the installation of car seats.

There is now an expanding global network of qualified and certified service partners who can produce expert solutions for specific requests.

A range of man-machine services and products now exist including robotic arms with a jointed arm pay-load from 3kg to over 500kg. In this case, linear robotic units move along horizontal tracking, increasing their working envelope. Stainless steel units are designed for environments with exacting requirements. High standards of hygiene, including sterilised environments are predominantly found in the medical and food industries. The anti-corrosive quality of stainless steel materials, allows for the use of chemical agents and high pressure cleaning equipment (fig 63), while maintaining a watertight surface area and the production in state of the art hand control systems for the robotic units. Software development is also at the forefront of robotic movement manipulation and interface capibalites, with a new Microsoft Windows based PC format now available.

fig 62

fig 63

In the 2002, James Bond film Die Another Day, directed by New Zealander Lee Tamahori, Kuka robots played a strategic role in the portrayal of the villain. James Bond (Pierce Brosnan) is desperately trying to save his current “squeeze” Minx, played by Haile Berry (fig 65), is faced with confronting four opposing gantry-mounted hanging Kuka laser robots mounted on horizontal tracks (fig 64). Meanwhile Minx is strapped to a bench in the middle of all this action . These robots normally employed to cut diamonds, combine to produce a sinister opponent for the helpless human subject.

Kuka in its press statement is quick to make it quite clear that while ‘delighted’ to be cooperating in this ‘bold’ and ‘imaginative’ Bond concept, in the real world a Kuka robot carving up a person would be ‘inconceivable’.


fig 64

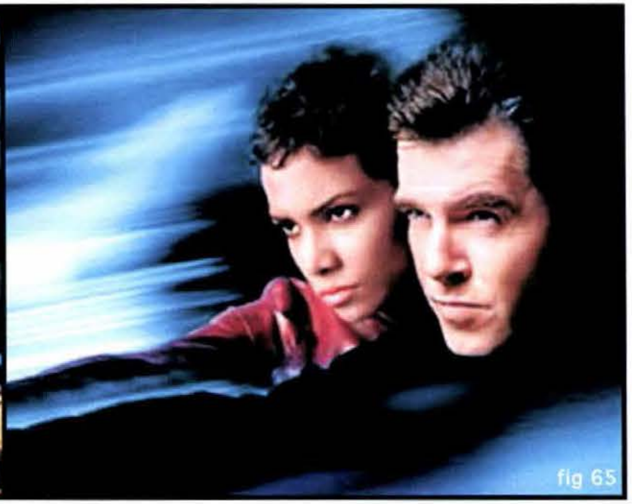


fig 65

Kuka claims the decision to use Kuka robotic technology was not just because of the robots’ ‘maneuverability’ and ‘good looks’, but also for the professional design and of course its ‘system support package’. While the latter is always an aim of a successful business venture and would have influenced the director’s decision to include the robots in the film, the visual form and presence created by these robots (as well as their functional attributes) would also have been influential. This break-away market for a product originally developed for the automation industry has ensured that design now plays an import role in the process of product image and identification.

7.0

state of art
myoelectric ergonomics


fig 66


fig 67

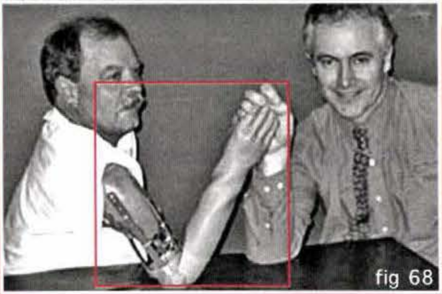


fig 68

humerus residual limb: myoelectrical nodes placed inside outer shell driven by localised muscle nerve endings

In 2004 at the International Society of Prosthetics and Orthotics Conference in Hong Kong, the German company Otto Bock HealthCare presented a fully robotic myoelectric artificial arm. The primary function of this arm was to allow transhumeral (above elbow) amputees the ability to regain the use of an amputated limb (figs 66/67). The aim of this project is to provide the user with the function of wrist and finger movement without hindering four pre-established factors or design criteria, they were power, noise, movement and response.

The Otto Bock Myoelectric Arm uses a variable (automatic) transmisson combined with a drive unit, which provides a direct drive to five separate motors that control movements in this artificial limb. Thumb, index finger, middle ring finger and little fingers are combined with wrist extension/flexon and wrist rotation in one unit. Electronic impulses from tissue nerve endings in the residual limb are filtered to control 3 dimensional movements. These functions produced by the Myoelectric arm are then attached to the amputee via a urethane socket mould and shoulder strap (depending on the individual). The outer shell or product casing is a blue rubber glove, while the interior consists of a structural alloy endo-skeleton (chassis). The functional criteria of this project dictates this product's exterior appearence.

Over the rehabilitation recovery period the amputees will come to regard this product as an extension of their body. While the functional attributes are groundbreaking, state of art examples of current research and development in the prosthetics industry, there is clearly a need to address the visual characteristics of this product.
In (fig 68) it is clearly obvious that while the machine aesthetic or structural form is addressed in the guise of a rubber glove and exposed metal strapping, little thought has been given to the missing natural aesthetic (myo-humanistic) form.

7.1

transtibial ergonomics
endo architecture

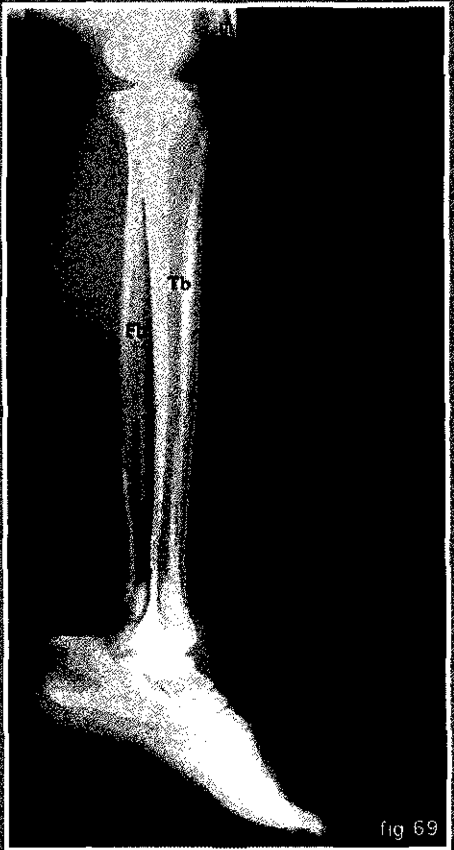


fig 69

endo-skeletal architecture
tibial (Tb)
load bearing bone of lower leg
fibula (Fb)
muscle attachment bone

The object of this ergomonic study is to understand the shape and form of the tibial region. Variations in a person's individual muscle groups are due to many different factors. Heredity genetic overtones, weight distribution, exercise, diet and age are some of the identifiable issues regarding an individual's overall physical form and well being. One initial observation that may be made at this point is that, to a varying degree, all relative muscled areas of an individual in a localised area are and will always be concurrent in action, to one another.

The endo-skeletal architecture of the human body is the platform from which the rest of the body's structure is attached. Certain bones in the human skeleton such as the ulna, (situated in the lower arm) and the fibula (situated in the lower leg) are designed to hold the surrounding muscle structure in place. While their coinciding partners (radius and tibia respectively) are solely used as load bearing.

If we consider how the lower extremity of the human body works during motion via a range of lever systems and expanding and contracting muscled areas, we can then understand why certain areas of the body are naturally shaped the way they are.

The human body is built on and around a framework of skeletal endo-architecture. There are 206 structural pieces of which the long bones of the arms, fingers, legs and toes are directly concerned with work load. An example of a visual characteristics of a long bone is the pictured tibial region (fig 69). This comprises of two long shafts attached together at two enlarged joint surfaces. The compact, dense and mostly smooth outer surface area of the bone surrounds a

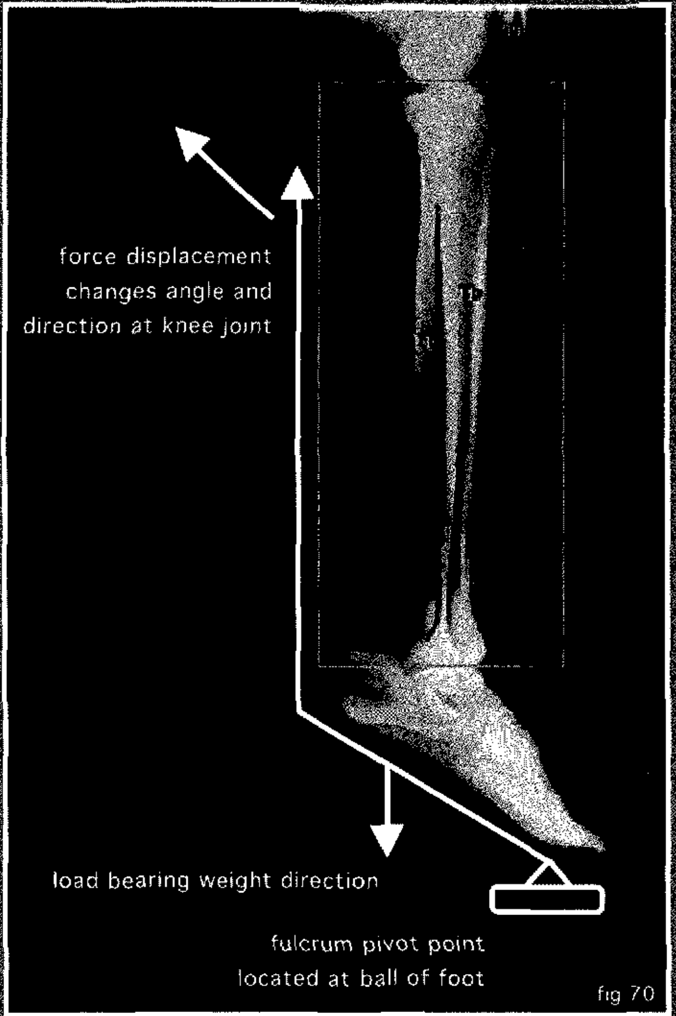


fig 70

central plated core that is significantly less dense, rougher and more open in structure. The various directions of the textured plates, asymmetrical in pattern are oriented towards directional strength in relation to the naturally applied forces. This natural structure is truely unique in engineering terms.

This endo-structure uses a collection of two systems of levers, the arms and legs, and a spine. This structure acts as operational lever system, connected together by joints covered in a cartilage frictionless surface. The forces which operate the lever system are applied through the muscles.

The walking movement action uses a very simple form of lever mechanics. This lever system varies in efficiency during motion. The efficiency of the movement depends on the position of the tendon's attachment to the skeleton, and its corresponding operative muscle group action. During joint movement there is always one position where a related muscle is working at its optimal mechanical advantage. As a joint is moved, the mechanical advantage changes throughout the variation in the direction of the pull of the muscles involved.

Figure number (70) replicates the ball of the foot under maximum load strain. Muscles in the ankle and foot are under optimal/maximum stress. The point at the end of the directional movement, the load fulcrum, is now static in nature. Each muscle must be able to reach and release from an optimal position during the various stages of motion. If for example the muscles were all fully loaded at the same time, an instant burst of energy on the maximum dynamic load would result in loss of control over the muscles and cramping. Muscles' tension will always be affected by the movement and positioning of the limb and joint.

7.2

myographic ergonomics
muscle architecture

fig 71

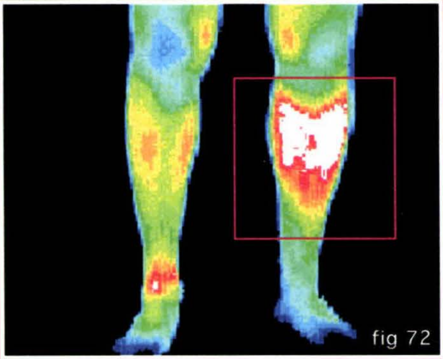


fig 72

transtibial amputation ergonomics

The sectioned amputation of the fiblua and tibia bones and removal of residual muscled surface area, dramatically places a new set of mechanical demands on the hip joint and its surrounding muscle tissue. The femur (upper leg), knee joint and amputated tibia and fibula bone now compensate for the extra stresses of a prosthesis. Removal of the musculature in particular the muscled trigger devices in the transtibial residual limb combined with the added deadweight places immediate strain on the lower back area at the centre point of gravity (fig 71).

[illegible] heat regulation

The body surface area of the average man is approxmitly 1.8 m^2. the head accounts for 17%, 19% in the arms, 29% in the legs and feet and 35% in the trunk. The body will produce up to 10 litres of sweat per day, depending on activity and climate. During extreme activity an encased residual limb (fig 72) will sweat up to 1.5 litres per hour over the total surface area (Blohmke, 2002). When clothed the rate of sweat evaporation diminishes; and the more insulation there is, the slower the rate of evaporation.

The body remains at an approximately constant temperature at all times. This is achieved by a mechanism that actuates body temperature at an equilibrium, where heat generated = heat lost. This balance and its level of regulation is dependent on the type and duration of activity. The peripheral muscles used during exercise can account for up to 75% of the heat generated within the body and will keep generating heat after the period of exercise. This is even more so during an aerobic exercise.

The regulation of heat throughout the body is achieved by the adjustment of the body's natural thermal insulation, or outer soft tissue areas, that allow the expansion and constriction of surface


fig 73

tissue blood vessels. Variations of heat loss from different parts of the body depend on the relationship of the surface area and the volume of that area, the degree of insulation or body fat and the distribution of sweat glands. Figure number (72) shows an example of heat build up in the upper tibial area when a transtibial residual limb is embedded in a socket.

With strenuous forms of exercise such as walking with an artificial limb, sweating is the means of disposing of surface heat. This is most effective when the body's surface area is completely covered in moisture. The evaporation of sweat is the principal means by which the body can dispose of excess heat. The rate of sweating depends on the surrounding air temperature and the relative humidity. The process of body heat disbursement requires the generated heat to be carried to the surface via the blood stream. The physical effect of increased heat production is an increase in blood flow and pulse rate. Once the surface veins in the skin become dilated, the surface temperature will increase. As the gradient between the surface and the environment increases sweating will begin. This moisture relies on evaporation for outer temperature control. Continuous heat build-up within the constricted area of the residual limb socket will lead to volume fluctuation, skin ulceration, residual pistoning and eventually prosthesis failure.

To understand how the lower tibial region works and why certain muscled areas are shaped, a detailed myographic study was performed. Various angles and perspective views were studied to identify external muscle movement and muscle group shaping when put under different strains and loads.

There are three types of uni-laterial contractable muscle groups in the human body, striped, or voluntary muscle, smooth muscle and cardiac muscle. The muscles in the tibial region contract in the one direction vertically down the length of the tibia and the fibula bones. The striped or

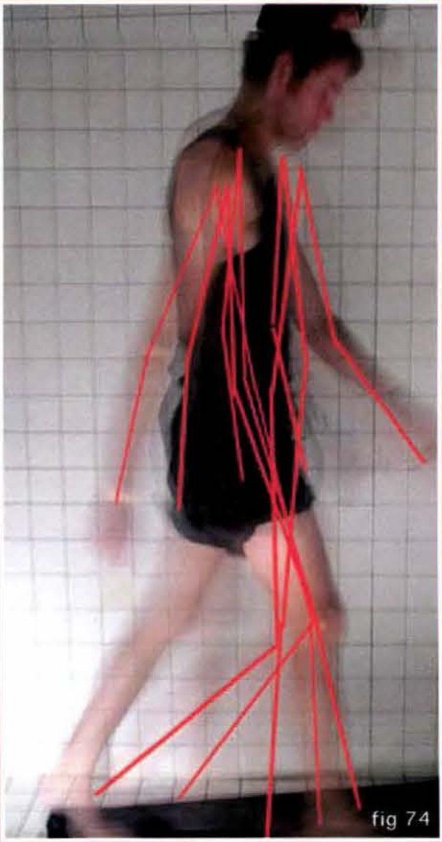


fig 74

voluntary muscle type supplies most of the voluntary movement. The long, thin and parallel cylindrical fibres are layered together and can be up to 30cm in length. Bundles of these fibres make up the bulk of the muscle. Muscle groupings are themselves not directly attached to the bone over the surface area (fig 73). The fibres of the muscle group change into collagen fibres which in turn combine into a bundle to form tendons. Tendons are attached directly to roughened portions or projections of the respective bones' surface. Various fibres that form a localised muscle grouping may not be attached to the same tendon. In this case a muscle may be attached to several separate parts of the body.

The contraction of a muscle fibre reduces it to roughly half its original length. General muscle movement depends on the length of the individual fibres. Muscle strength depends on the number of fibres contained in the muscle. A compromise is needed between fibre length and fibre density to function successfully. Muscles with a great amount of movement exert little force hence a muscle with a high-fibre density and little length exerts the most force. Individual muscle fibres operate on a required non-required principle. As a graduated movement is required, more fibres are successively brought into operation (fig 74).

Repetitive over-use of muscle have two commonly recognised behavioural patterns, muscle hypersensitivity and muscle cramping. The first behaviour of an over-exercised muscle is that it may not be able to stay in a relaxed state when rested, this results in residual tissue activity or muscle tremor. Muscle cramping is the product of spontaneous contraction of all the muscles in a localised area. During over-exertion and/or sudden movement, an individual may use other muscles to carry out the same task to compensate when pain occurs. Muscle incapacity can arise from either sudden exercise of force or continuous exercise over a long period.

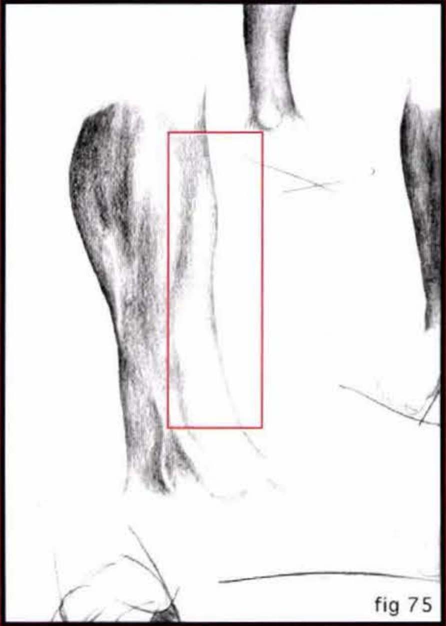


fig 75

One example of tibial regioned muscle damage, is permanently impaired movement. The muscle (tibialia anterior) (fig 75) that runs down the front of the tibial bone from the knee to the inside ankle is used to hold up the toe when raised above its normal position. An example of this is the position the toe takes when pedalling on a bicycle in an upward stroke. The muscle in this scenario is used continuously during a normal day. Prolonged usage in this position may cause intra-muscular fluid accumulation. Due to the unique position of the muscle held against the tibia by layers of fibrous tissue, fluid dispersion, if it occurs at all, is minimal.

Muscular development in the lower leg will vary with different individuals. If the bulk of a muscle group is too great it will interfere with the limb movement.

Subconsciously, the natural shape of the tibial muscled area is recognised as an individual's own unique leg shape. Should that limb then be removed as a result of trauma, what then happens to an amputee's sense of personal identification?

Does an amputee suffer from not just the trauma itself, but the ability to comprehend that there is now an empty space where once a lower limb resided?

7.3

ergonomics
anthropometrics of walking

gait analysis and the gait cycle

The measurement and alignment of any standing, walking and running stride is called the gait cycle. The components of this cycle are split into two stages, the static phase (stance) and the dynamic phase (swing). The static phase of a leg's movement is when it bears a load and is in whole or part in contact with the ground. The dymanic phase is when the leg is in motion and bearing little or no load and is mostly free from touching the ground or not in contact at all.

There are three tasks the gait cycle is responsible for (fig 76). The first is the weight acceptance of the transfer of body weight onto the limb that is coming to a stand still or is at the end of its swing phase. At this stage the limb has an unstable alignment with the ground. The second task is the single limb support position. One limb is supporting the entire body weight, this in turn provides stability and progressive forward momentum. The third task is limb advancement. This requires foot clearance from the floor to allow the limb progression through to its most forward destination.

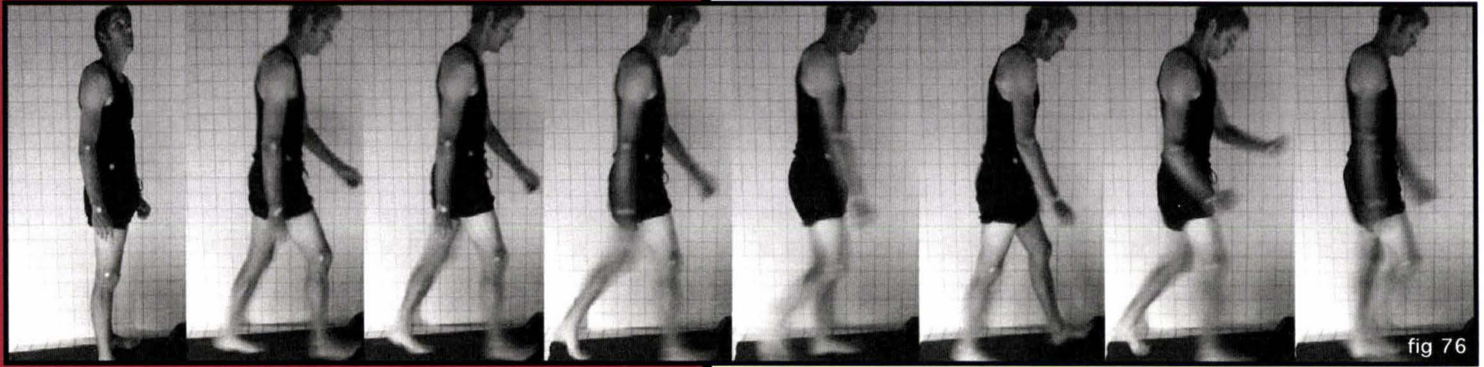


fig 76

There are eight sub-phases of the static and dymanic gait cycle. They are initial loading, loading response, mid-stance, terminal stance, pre swing, initial swing, mid-swing and terminal swing. These are broken down into the various stages of weight loading and distribution during the gait cycle.

7.4

ergonomics
eight stage sub cycle
swing phase

The following photographs show the swing phases of the eight phase gait cycle (figs 77/78). PHASE ONE: INITIAL LOADING. The phase of movement is when the right foot touches the floor and is under dynamic load. In most cases the heel is the first part of the foot to touch the ground during walking motion and the ball of foot when jogging. In both cases the hip is fixed, the knee is extended and the ankle is in dorsiflexion to neutral position. The left leg is at the end of its terminal stance.

PHASE TWO: LOADING RESPONSE. This is the double stance action beginning when the foot contacts the floor and continues until the other foot is lifted for the swing phase. Body weight is transferred onto the right foot. Phase two is important for shock absorption, load bearing and forward momentum. The next task of the gait cycle involves single limb support. The entire body weight is supported by one limb while maintaining and providing stability and forward motion respectively.

fig 77

PHASE THREE: MID STANCE. The first half of the single limb support interval. The lifting of the left foot forward until the body weight is aligned over the supporting right foot. As the right leg advances over the right foot by ankle dorsiflexion while the hip and knee extend, the left leg is advancing in its mid-swing phase. The right leg is load-bearing and static in motion at mid-stance while the left leg is non-load bearing and dynamic in motion.

PHASE FOUR: TERMINAL STANCE. The right heel rises and continues until the heel of the left foot touches the ground. As the weight of the body continues forward beyond the right foot, increased hip extension puts the leg in a trailing position.

PHASE FIVE: PRE SWING. This is the second double stance interval in the gait cycle. This cycle begins with the initial contact of the heel of the left foot and ends with the toe of the right foot leaving the ground. Ground contact of the left leg causes the right leg to increase ankle flexion, increase knee flexion and decrease hip extension. Transfer of weight from load bearing (static right foot) and limb to the dynamic left foot and limb takes place.

PHASE SIX: INITIAL SWING. This phase begins when the foot is lifted from the floor and ends with the swinging foot opposite the static stance foot.The right leg is advanced by increased hip and knee flexion. The ankle only partially flexes to ensure ground clearance. The left leg is in mid-stance.

fig 79

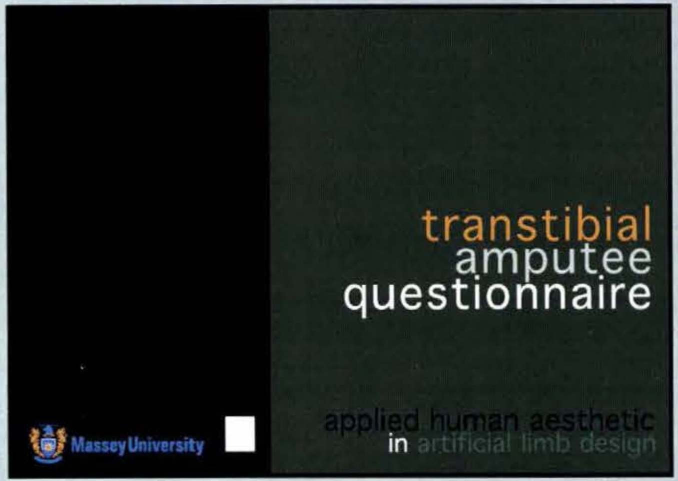
PHASE SEVEN: MID SWING.

This phase continues from the end point of the initial swing (phase six) and continues until the swinging limb is in front of the body and the tibia is vertical in postion. The right leg is advanced further by hip flexion. The knee is able to extend in response to gravity. The left leg is in late mid-stance.

PHASE EIGHT: TERMINAL SWING. The movement begins when the tibia is vertical and ends when the foot touches the floor. Limb advancement is completed by the extension of the knee. The hip maintains its flexion and the ankle remains dorsiflexed to neutral.

8.0

qualitative research
transtibial amputee questionnaire
overview


transtibial
amputee
questionnaire

applied human aesthetic
in artificial limb design

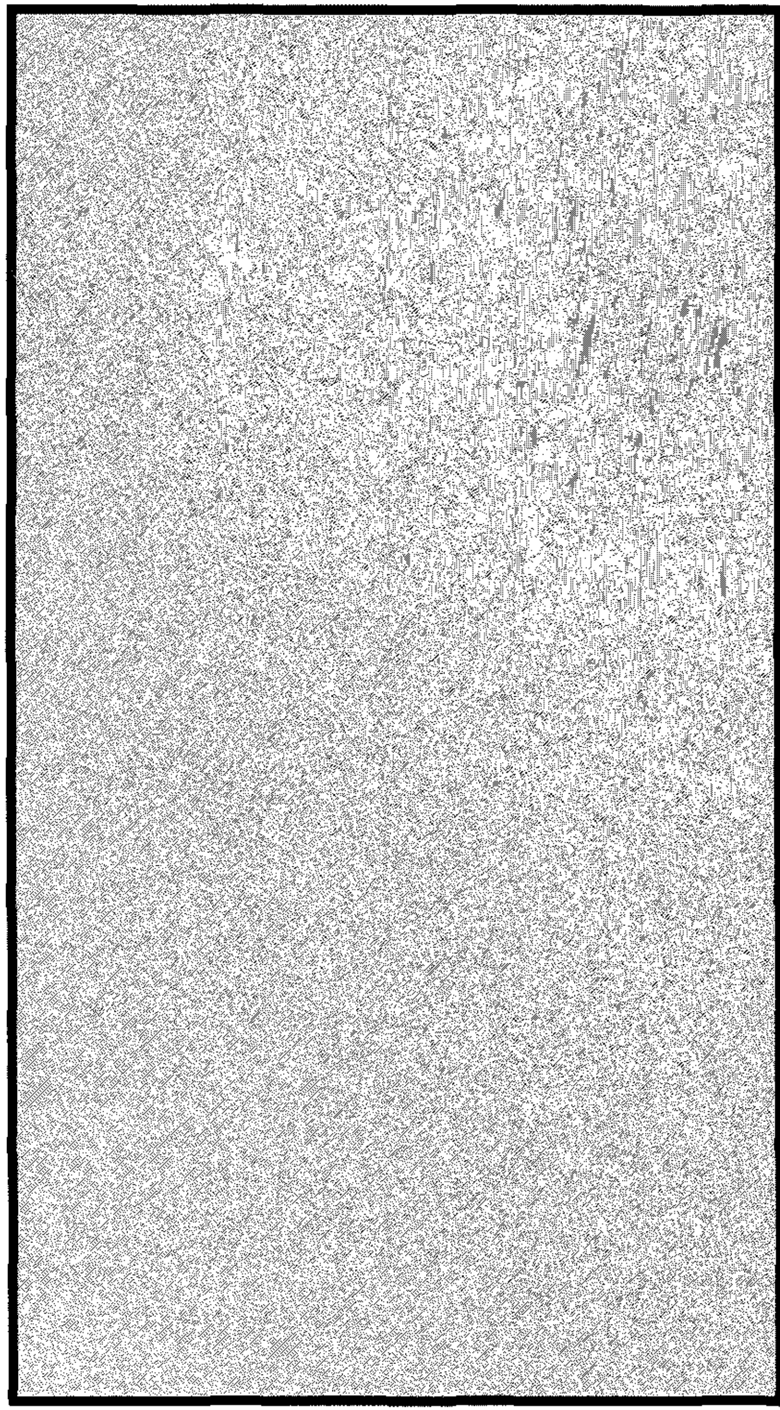
Massey University

The development of a questionnaire was required to gather qualitative information from a 'physically active transtibial amputee' user pool group. Transtibial amputees' personal aesthetic preferences are not currently considered during the artificial limb research and development process. The functional priorities of artificial limbs are currently dictating the visual aesthetic of prosthetics.

The development of questionnaires intended for user pool groups identified as patients or clients of any organisation providing health services in New Zealand requires Massey University Human Ethics Committee and New Zealand Health and Disability Ethics Committee approval.

The initial aim of this qualitative questionnaire was to define the personal visual aesthetic values of transtibial amputees regarding their artificial limbs.

Initial planning of the questionnaire required a research direction and a qualitative research structure. Informal discussions were held with two transfemoral (above knee) and three transtibial (below knee) amputees attending the ISPO Conference in Hong Kong during the first week of August 2004. Some of the issues discussed included the aesthetic behaviour of their current artificial limbs, how they could be improved visually and what improvements they would like to see personally. All of the amputees indicated an interest in design with some expressing surprise that no one had previously discussed the aesthetic value of an artificial limb with them. There were two female transfemoral amputees in their mid-20s who were very interested in the form of their replacement limbs. Both agreed that the missing volume and form from the current artificial limb they used impact on their sense of identity. They both mentioned that because of the visual aspect of their artificial limbs, they often, if not always covered up their limb when



going out. It was only ever during exercise that their limbs were visually exposed. Embarrassment of their disability, fear of being pre-judged, low self-esteem and the impact on personal identity were all issues identified by amputees as concerns . Every amputee that I talked to during the conference expressed a lot of interest in the outcome of this study. The general consensus was that there is not enough currently being done to develop and address the visual appeal of artificial limbs. All recognised that the industry is driven by functional research and development and little work is put into the visual aesthetic. A simple pilot questionnaire was then developed and sent to the two female amputees I had previously chatted to in Hong Kong, which they both agreed to evaluate and return with their suggestions. Their feedback indicated that the questionnaire should focus on the aesthetic appeal of artificial limbs; questions should be personal and informative so amputees are able to relate to the topic; and questions should be kept simple and the use of technical terms kept to a minimum.

The development of the questionnaire involved three main phases. The first of these was the planning phase. Consideration had to be given to advantages and disadvantages of the form of questionnaire, its structure and development, objectives, feasibility, administration and definition of a sample group. The result of phase one was the distribution of an anonymous questionnaire among active transtibial amputee patients at the Wellington Artificial Limb Centre. The main reasons for selecting these patients were their availability, ease of questionnaire access and administration. Working closely with the NZALB and Dr Judith Davey from Victoria University, a qualitative questionnaire was formulated from the original pilot questionnaire. A second sample pilot questionnaire was then tested anonymously.

The second phase involved seeking approval from both the Massey University Human Ethics Committee and the NZ Health and Disability Ethics Committee to distribute the questionnaire. Due to the status of suggested participants, patient access issues required forward planning with permission firstly being requested through the New Zealand Artificial Limb Board and the Wellington Artificial Limb Centre.

Phase three involved the distribution and administration of the questionnaire by staff at the Wellington Artificial Limb Centre. All responses were returned directly via a self-addressed envelope or via associated staff at Wellington Artificial Limb Centre.

This design development study questionnaire requires all participants to be physically active *transtibial amputees*.

This study requires amputees to evaluate their artificial limb's visual aesthetic and basic functional performance.

The primary participant criteria are people who are:

- trauma amputees;
- uni-lateral or bi-lateral transtibial amputees;
- adult;
- male and female;
- physically active on a week by week basis.

The definition of the term 'physically active':

- requires participants who travel at least 2km per week under their own devices.

[An equivalent distance is five laps around a rugby field]

The objective of this questionnaire is:

1) - To establish how users of transtibial artificial limbs feel about the appearance of their limbs;

2) - To ask users how the appearance of their artificial limbs could be improved.

The administration of the questionnaire is as follows:

a) 30 numbered questionnaire packages will be forwarded to New Zealand Artificial Limb, Wellington.

b) Participants identified as 'active transtibial amputees' by New Zealand Artificial Limb staff.

c) All participants will be selected and approached by a staff member from New Zealand Artificial Limb, Wellington.

d) Participants will receive a questionnaire package with letter of introduction.

e) Participants must read all information provided before undertaking answering the questionnaire.

f) Participant completion and return of questionnaire implies consent.

g) A self-addressed, postage paid, RETURN envelope is provided.

h) Participants are asked to return questionnaire answers within 30 days of receiving the questionnaire package.

This design development study questionnaire requires all participants to be physically active transtibial amputees. Amputee participants will evaluate the visual aesthetic and basic functional performance of their prosthesis/artificial limb(s).

Questionnaire participants must meet the following criteria:

- trauma amputees;
- uni-lateral or bi-lateral transtibial amputees;
- adult;
- physically active on a weekly basis. (Participants are able to travel at least 2km per week under their own device or without assistance. e.g. wheelchair) An equivalent distance is 2-3 laps around the Basin Reserve, Wellington.

To whom it may concern.

My name is Daniel Buxton. I am currently undertaking a post-graduate study in Industrial Design at Massey University College of Creative Arts, Wellington. This study is titled Applied Human Aesthetic in Artificial Limb Design.

The aim of this questionnaire is to find out what you think about the visual appearance of your artificial limb.

- Do you like the way it looks?
- Do other people like the way it looks?

My research to date suggests that transtibial artificial limbs provide users with the functions they require for mobility. What about the visual quality of these artificial limbs?

What do you think about:

- your cultural identity;
- social interaction;
- rehabilitation recovery time;
- self-esteem;
- personal identity.

What do you think about these issues?

I would like to know.

STATEMENT OF RIGHTS:

You are under no obligation to accept this invitation.

If you decide to participate, you have the right to:

- decline to answer any particular question;
- withdraw from the study;
- *ask any questions about the study at any time during your participation;*
- provide information on the understanding that your name will not be used unless you give permission to the researcher;
- be given access to a summary of the project findings when it is concluded.

COMPLETION AND RETURN OF THE QUESTIONNAIRE IMPLIES CONSENT.

This project has been reviewed and approved by the Massey University Human Ethics Committee, Palmerston North Application 05/28. If you have any concerns about the ethical content of this research, please contact Dr John G O'Neil, Chair, Massey University Campus Human Ethics Committee:

PN telephone 06 350 5799 x 8635, email: humanethicspn@massey.ac.nz

If you agree to participate in this anonymous questionnaire please read all attached documents.

At no time are these questions designed to cause offense.

Please return your completed questionnaire in the self-addressed envelope provided.

If you have any difficulties or questions regarding this questionnaire or my study, I can be contacted directly at:

email: D.Buxton@massey.ac.nz   mobile: 0274996209

Supervisor: Dr Duncan Joiner, Professor of Design, College of Creative Arts, Wellington.

email: D.A.Joiner@massey.ac.nz

TO ALL PARTICIPANTS

Please read this privacy and confidentiality statement carefully.

The questionnaire titled 'Transtibial Amputee Questionnaire' is a Masters Industrial Design study by Daniel Buxton, at the Department of Industrial Design, College of Creative Arts, Wellington, New Zealand.

Terms and Conditions:

- Please return questionnaire in supplied envelope, by August 25, 2005.
- All participants have been identified and chosen by staff from the Wellington Artificial Limb Centre, New Zealand.
- All information gathered in this questionnaire is considered strictly private and confidential and the property of Daniel Buxton and Massey University College of Creative Arts.
- Participants are entitled to request copies of the questionnaire findings after the study has been completed, from Wellington Artificial Limb Centre staff.
- All design ideas, concepts and data gathered from the questionnaire are to be considered private and confidential at all times and will not to be discussed with third parties.
- At NO time will any data gathered from questions be shared with any other parties other than those listed above.

The questionnaire will remain anonymous. At no time will your identity be revealed in this study.

- All other information gathered in this questionnaire will be published by Daniel Buxton in the Masters study titled 'Applied Human Aesthetic in Artificial Limb Design' at Massey University Department of Industrial Design, College of Creative Arts, 2004/05.

8.1

transtibial amputee questionnaire results

The following provides a summary of the qualitative questionnaire conducted at the Wellington Artificial Limb Centre during August 2005.
Of the 30 questionnaires handed out by staff to transtibial amputees, 27 completed questionnaires came back by the cut off date of August 25, 2005.

Participant gender
Of the 27 physically active transtibial amputee participants, 15 were male and 12 were female.

Participant age group
The age group ranged towards a senior demographic with no participants in the 25-29 age group and one in the 18-24 age group. a) 18-24 b) 25-29 c) 30-39 d) 40-49 e) 50-59 f) 60+ years

participant gender

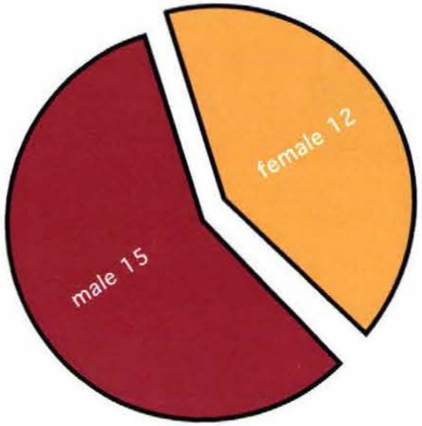


table 16

participant age group

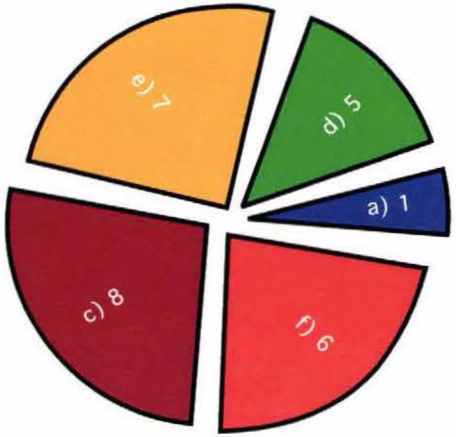


table 17

1) Amputee duration

12 participants questioned have been amputees for the duration of 1-9 years Seven have been amputees for 10-19 years.

a) Under 1 year b) 1-9 years c) 10-19 years d) 20-39 years e) 40+ years

2) Amputation identification

All amputee participants are single below knee amputees.

3) Artificial limb usage

17 participants used their artificial limb mainly for stability and movement. No participants used their artificial limb as a visual aid.

a) Stability and movement b) Visual aid c) Both stability, movement and as a visual aid

4) Physically active

16 participants considered themselves physically active while 11 considered themselves not physically active on a day to day basis.

1) amputee duration

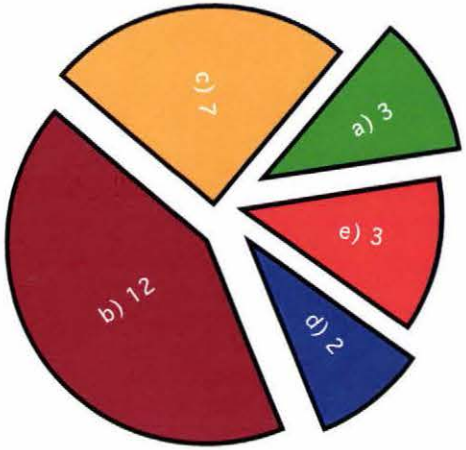


table 18

2) amputation identification

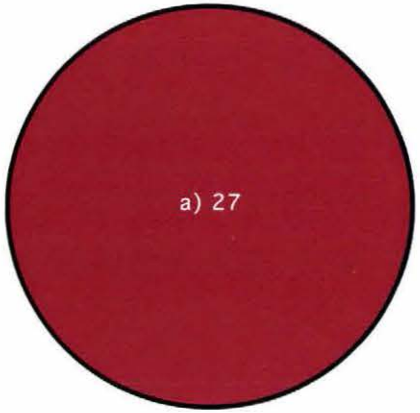


table 19

3) artificial limb usage

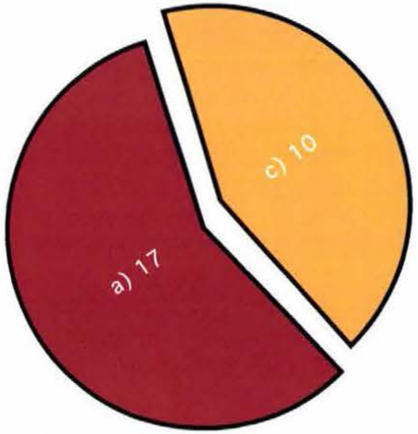


table 20

4) physically active

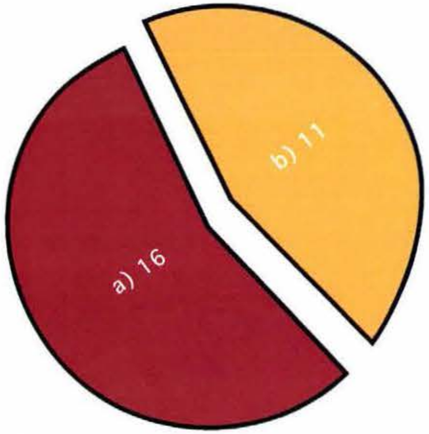


table 21

5) Amputee distance

The distance travelled on foot by the participants during a week ranged evenly over the demographic with slightly more travelling up to 2km per week.

a) up to 2km b) between 2km and 5km c) between 5km and 10km d) more than 10km per week

6) Individual sporting activity

16 amputees do not participate in individual sporting activities while 11do so on a weekly basis.

6a) Individual sporting activity duration

Of the 11 amputees who participate in individual sporting activities, 1 person did so every day, 7 amputees did so 2-6 times a week and 3 participated once a week.

7) Team sporting activity

Only one amputee participated in any form of social team sporting activity.

5) amputee distance

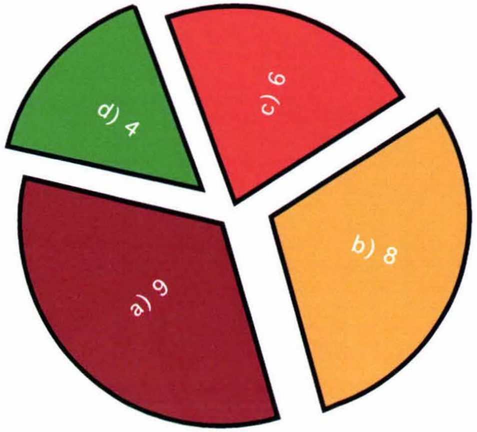


table 22

6) individual sporting activity

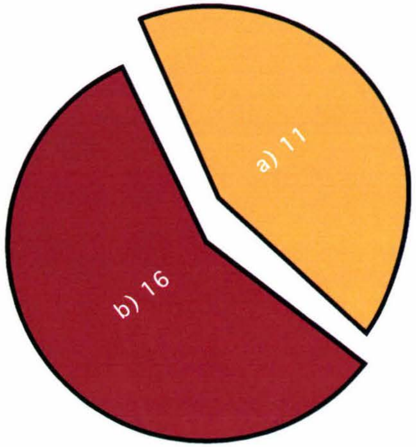


table 23

6a) individual sporting activity duration

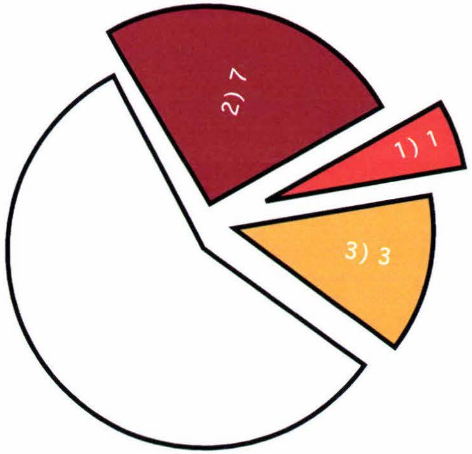


table 24

7) team sporting activity

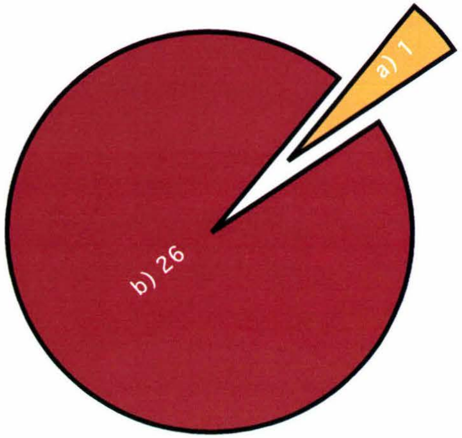


table 25

7a) Team sporting activity participation
One amputee has participated in a social team sporting activity once a week.

8) Extreme sporting activity
Only three amputees have participated in an individual extreme sporting activity of some kind.

8a) Extreme sporting activity artificial limb usage
Three amputees who participated in an extreme sporting activity were wearing their artificial limbs at the time while two amputees did not.

9) Artificial limb breakage
19 participants had never broken their artificial limb during any sporting activity. One had often, two sometimes had and five had rarely broken their artificial limb during any sporting activity.

7a) team sporting activity duration

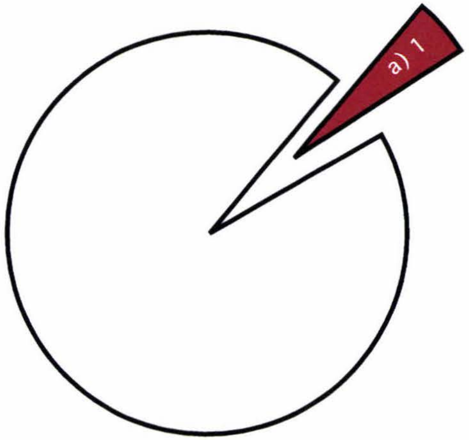


table 26

8) extreme sporting activity

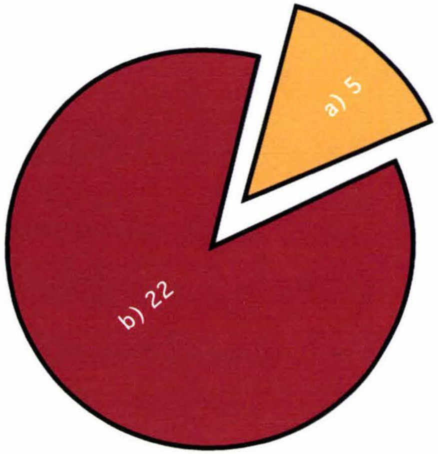


table 27

8a) extreme sporting activity artificial limb usage

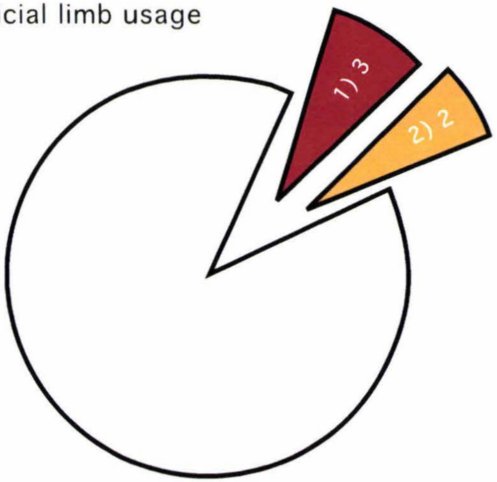


table 28

9) artificial limb breakage

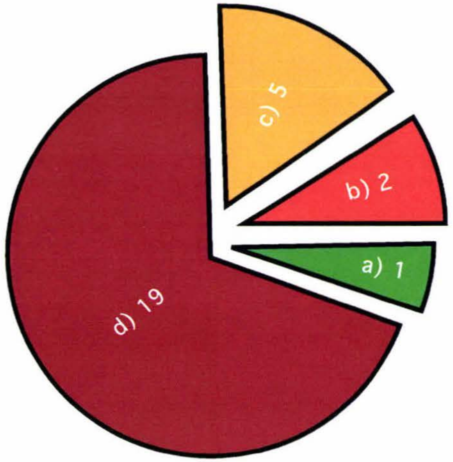


table 29

10) Artificial limb durability
All selected participants considered the durability of their artificial limb an important issue in its everyday usage.

11) Lifestyle
24 participants said the visual appearance of their artificial limb suited their current lifestyle, three said it did not suit their lifestyle.

12) Overall appearance
Only 2 participants considered that the overall appearance of their artificial limb could be drastically improved while no one considered it needed to be completely changed. Six amputees were very happy with the appearance, 12 were happy, seven considered it could be slightly improved, while two said it could be drastically improved.

15) Artificial limb visual embarrassment
No amputees were always embarrassed by their artificial limb. 14 had never been embarrassed by its visual appearance.

10) artificial limb durability

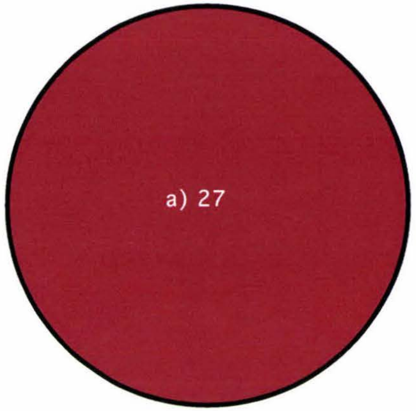


table 30

11) lifestyle

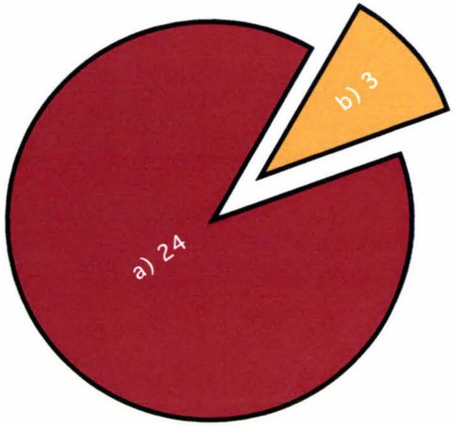


table 31

12) overall appearance

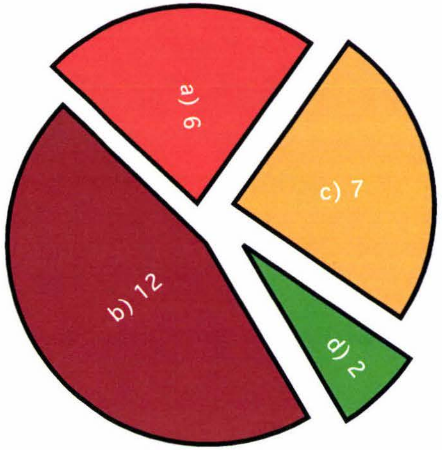


table 32

15) artificial limb visual embarrassment

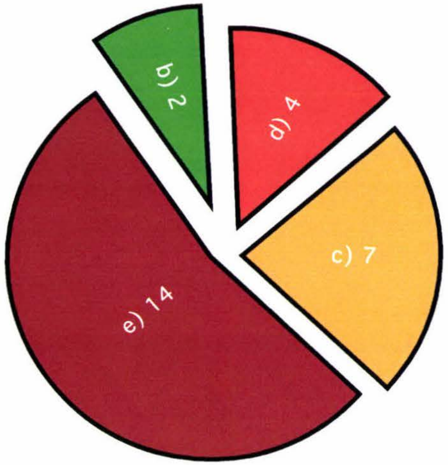


table 33

17) Natural shape

21 participants think that the natural shape of their leg should be taken into consideration when a new artificial limb is produced for them while 6 do not mind.

18) Human machine visual quality

9 participants think if an artificial limb looks machine-like rather than human, they may be less willing to use it. 18 participants do not mind.

19) Visual capacity

14 participants believe that an artificial limb should have the capacity to 'show off' or 'celebrate' their disability while 13 do not.

20) Rehabilitation capacity

21 participants consider the visual form of an artificial limb to neither assist nor hinder the rehabilitation process. Five claimed it assisted and one said it hindered the rehabilitation process.

17) natural shape

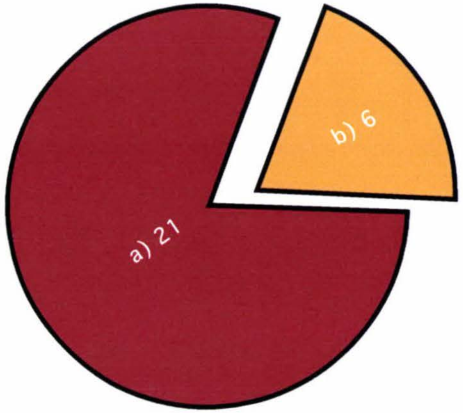


table 34

18) human machine visual quality

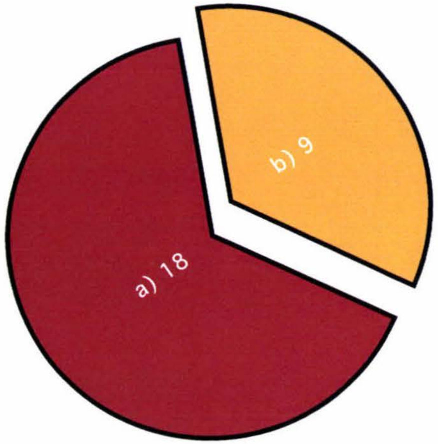


table 35

19) visual capacity

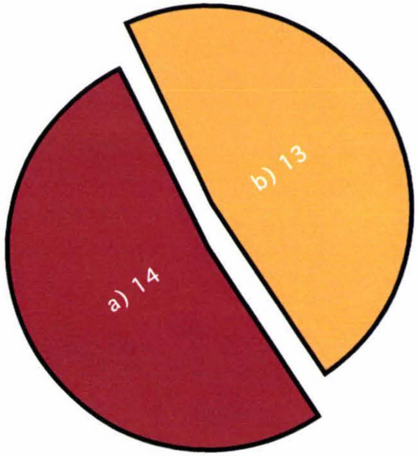


table 36

20) rehabilitation capacity

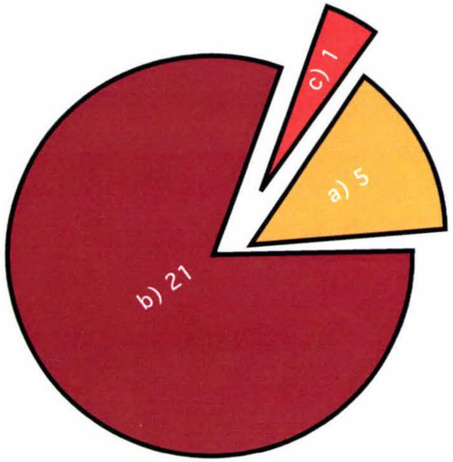


table 37

21) Rehabilitation recovery time

17 participants agree that a personally customised artificial limb which they helped design could benefit their rehabilitation recovery time. Nine did not believe it would make a difference. One participant was undecided.

22) Functional requirements

18 participants agreed that functional requirements are given a higher priority than the visual appearance of an artificial limb. Seven neither agreed nor disagreed and two disagreed.

23) Function and visual form

19 amputees agreed that how their artificial limb works is more important than what it looks like. Seven agreed both function and form is important and one said visual form is more important.

24) Visual replication

17 participants believe an ideal artificial limb is one that looks exactly like the missing limb, eight disagree two are undecided.

21) rehabilitation recovery time

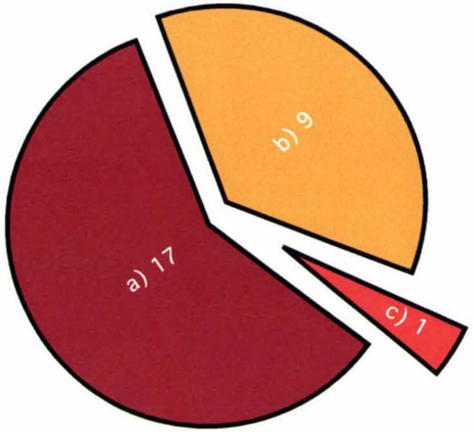


table 38

22) functional requirements

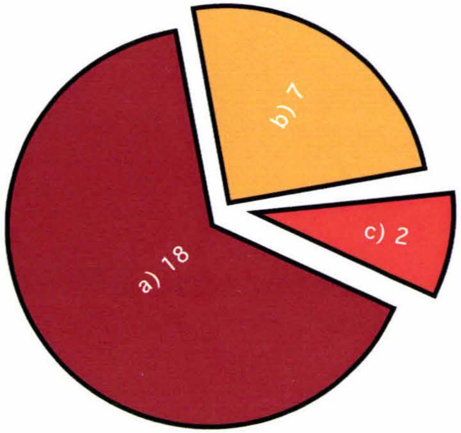


table 39

23) function form

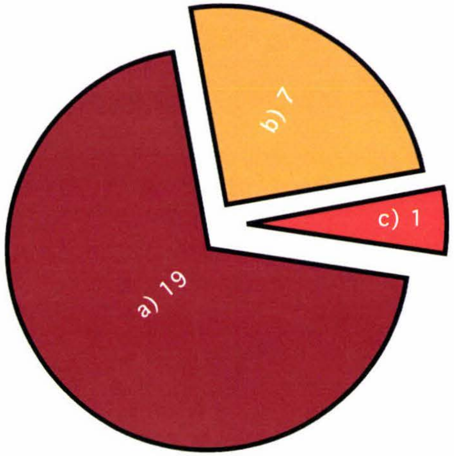


table 40

24) visual replication

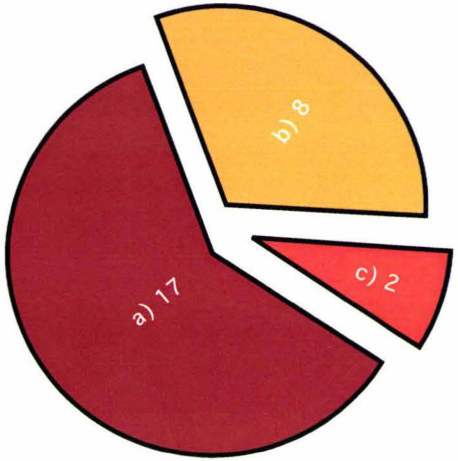


table 41

25) Natural skin colour

26 participants wanted to have the option of choosing their natural skin colour for their artificial limb.

26) Skin colour range

23 participants would like to see a wider range of artificial limb skin colour options that they can choose from, four did not.

27) Graphic options

The graphic options available for an artificial limb produced a mixed result with 15 participants interested in various options while 12 were not interested.

28) Relationship with clothing

Participants responses were varied with seven noticing their artificial limb catching on their clothes' four often noticed, five sometimes, six rarely and five never noticed their clothes catching.

25) natural skin colour

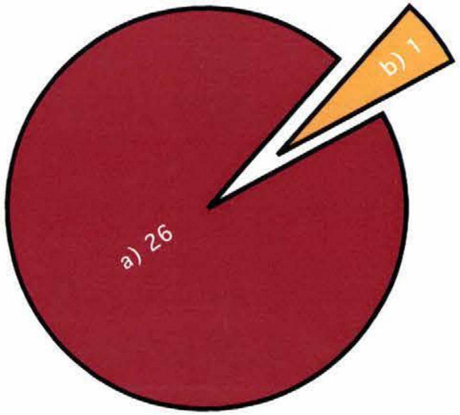


table 42

26) skin colour range

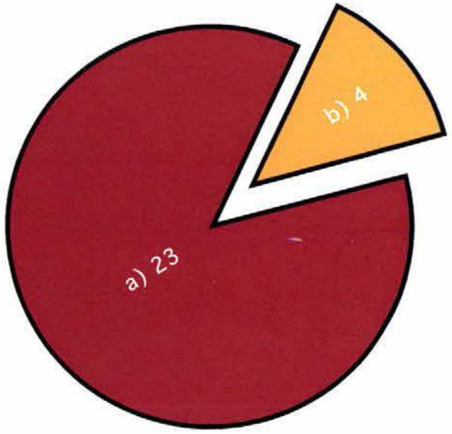


table 43

27) graphic options

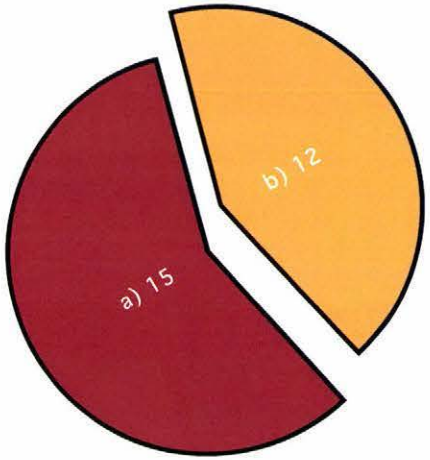


table 44

28) relationship with clothing

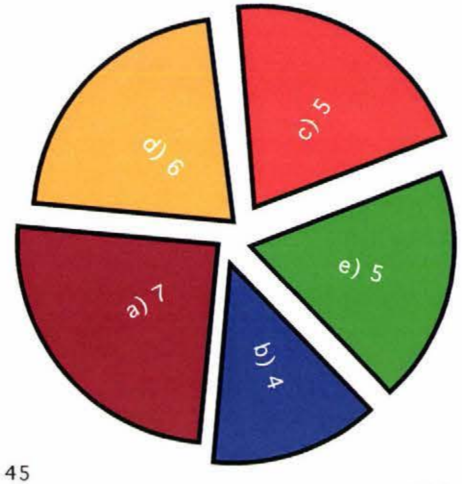


table 45

29) Sound quality

18 participants acknowledged that they noticed the sound of their artificial limb produced during activity, nine did not.

29a) Sound quality obtrusiveness

Of the 18 participants who noticed the sound, three said it was slightly obtrusive, eight said it was noticeable, one participant said it was very obtrusive and six claimed it was annoying during activity. No participants responded that the noise from their artificial limb was unbearable.

30) Amputee design access

20 of the participants agreed that they would like to be able to contribute to the design and development of their artificial limbs, seven participants were not interested.

29) artificial limb sound during activity

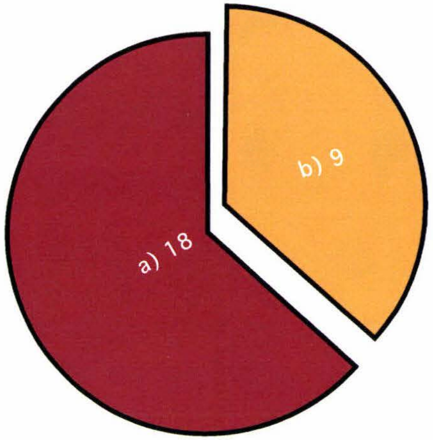


table 46

29a) sound obtrusiveness

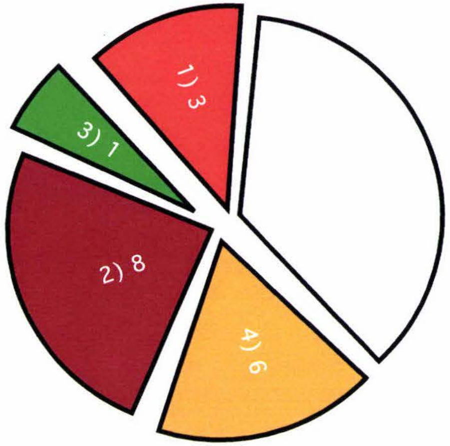


table 47

30) amputee design access

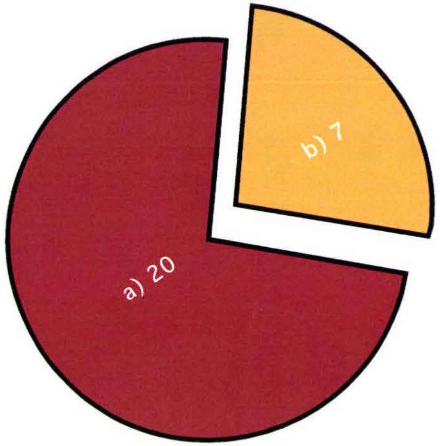


table 48

questionnaire discussion

13) visual appearance preference

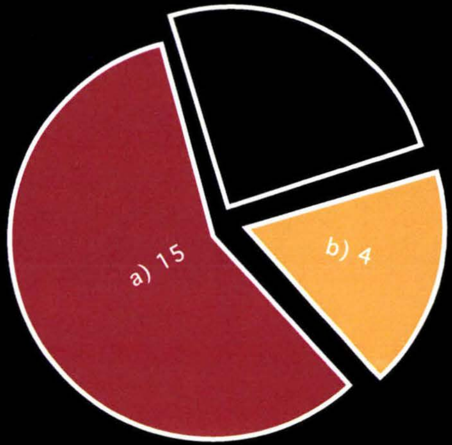


table 49

The overall response from participants regarding this questionnaire has been very positive, with only one male participant regarding this questionnaire as a 'no interest' topic. Ironically he still took the time to answer all the questions.

Questions 13, 14 and 16 provided the participants with the opportunity to comment on their artificial limbs. Their answers are as follows.

Question 13. What do you like best about the visual appearance of your artificial limb?
- 'That it looks technologically efficient and state of art for its purpose'.
- 'I have a limb that functions like a leg'.
- 'I like the shape but not the finish'.
- 'I like the carbon fibre, it is 'flash' and it shows others that we can do anything they can'.
- 'The shape is similar to a real leg'.
- 'Durable, it takes the knocks'.

Out of the 19 participants who answered the question a majority 15 (a) claimed that it was the shape and corresponding function of the artificial limb that they liked the most. It resembled and worked like the missing limb. Skin colour and graphics are also mentioned in this evaluation on an individual basis. A much smaller all male group (b) of participants said they liked the leg because it looked machine-like and was made out of materials like carbon fibre and shiny metal. It is clear to see that most transtibial amputees would like their artificial limb to resemble the natural limb that is missing as realistically as possible.

16) individual comments

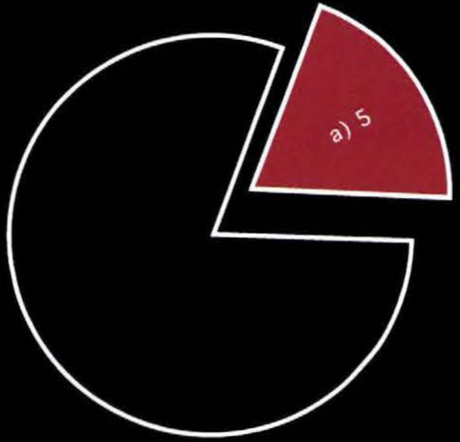


table 50

Question 14. What do you like least about the visual appearance of your artificial limb?

There were a wide range of responses to this question including among other things function, shape, colour and suspension attachment. Comments included:

- 'It can look shabby'.
- 'Thickness of leg around the attachment'.
- 'Black rubber lining covers the graphics and carbon fibre'.
- 'Lacking natural missing limb size'.
- 'Fake skin does not look like skin'.
- 'Hard to keep clean'.
- 'Fills with water and mud' and 'ruins my trousers'.
- 'It would be good to be able to use the same artificial limb for lots of different uses'.

One participant did not like the fact that the artificial limb did not have hair on it.

While refining the general functional requirements of the amputees artificial limbs is outside the scope of this study, the consensus among participants is that the aspects of both visual form and natural volume are important issues that could be addressed further.

Question 16 asked participants if they would like to comment on an embarrassing situation in public regarding their artificial limb.

Only five (a) participants did comment, mostly in relation to the public reaction when swimming or at the beach. These participants also seemed more concerned about other people's embarrassment than their own sense of discomfort in public. A participant was 'unhappy about the way it looks deformed when they are seated'.

Participants had an opportunity to add general comments of interest at the end of the questionnaire. Comments included:

- 'Artificial limbs should not cause discomfort to the amputee'.
- 'Making it function like a normal leg'.

8.3 questionnaire summary

- 'I feel very fortunate that my limbs are generally good functionally and cosmetically'.
- 'I'd love a limb that looked fantastic'.
- 'Visual appearance is of minor importance relative to comfort and functionality'.
- 'Patience can be required as we amputees often want to do activities and wear performance limbs that our 'stumps' just are not ready to handle. It can take years. Good idea this project thanks'.
- 'I am not big on displaying my prosthesis because it is so noticeable that it is not a real leg. I would not like to trade comfort for looks'.

The overall consensus of all the participants is that the functional qualities are more important than the final visual form. Nevertheless there appears to be room for improvement in both categories. While design currently plays little part in the current artificial limb research and development process, it is suggested that amputees should be more involved in this process. There is also a notable lack of communication between amputees and manufacturers about prosthetic design because generally amputees do not choose the artificial limb they are given and prosthetists can only choose what manufacturers supply them with. Clearly an amputee's personal identity, satisfaction and well-being are major factors in their rehabilitation and recovery. Although product form will always take second place to product function in this industry, design is still an important aespect of prosthetic development that deserves more attention. The results from this questionnaire bear this point out.

It must be mentioned at this point that the support and service of staff at the Wellington Artificial Limb Centre and New Zealand Artificial Limb Board has been invaluable to all participating amputees and their appreciation has so far gone unmentioned. New Zealand Artificial Limb staff are at the forefront of and a credit to their profession. Participating amputees and the researcher are enormously grateful for their support.

9.0

exo product architecture
the designed aesthetic

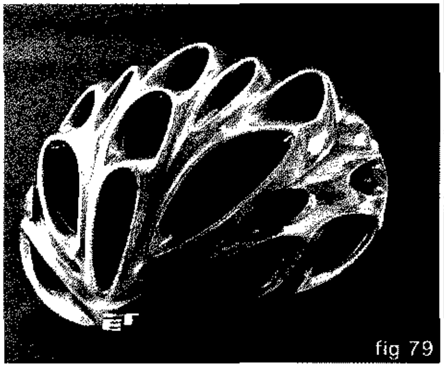


fig 79

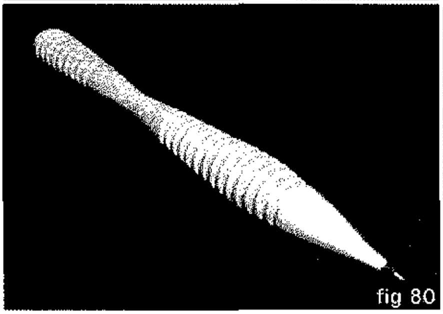


fig 80

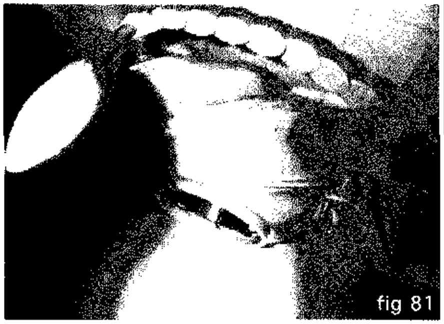
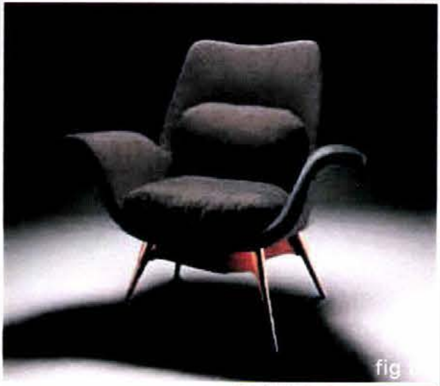


fig 81

It is in many circumstances, desirable to design a product that can be configured for individual needs and specialised requirements. Although these configurations can be limiting, they are required to fulfil market demand and should be incorporated into a product design criteria. To enable an adequate level of personalised individual preference, the design of a product should consist of variable functional criteria. To achieve this variability, some products rely on exo-product architecture.

Exo-product architecture is not only about creating a product's visual identity, it is about providing holistic and variable design platforms as a structural point of departure. In (fig 79) the ET cycle helmet demonstrates the concept of exo-shell architecture. In this case it is used to protect a cyclist from head injury. While this part of the product's functional criteria does not include any variables, its ability to house different sizes of head is a variable. To achieve this criterim without increasing the manufacturing and production costs, the product's ability to cater for various head sizes is built into an exo-shell or structural architecture. In doing so, the product achieves two goals; firstly it allows the functional criteria to be maximised thus increasing the market for the product, and secondly it incorporates a visual brand identity that is unique in shape and form.

The bio-ro (fig 80) is a biodegradable pen produced from recycled plastics. Its functional criteria are that it is to be used as a pen, then once it has run out of ink it can be thrown out safely without affecting the environment because its exo-shell has the ability to decompose. This product's design criteria is multi-faceted. It is a pen, it is ergonomically designed to be comfortable



fig

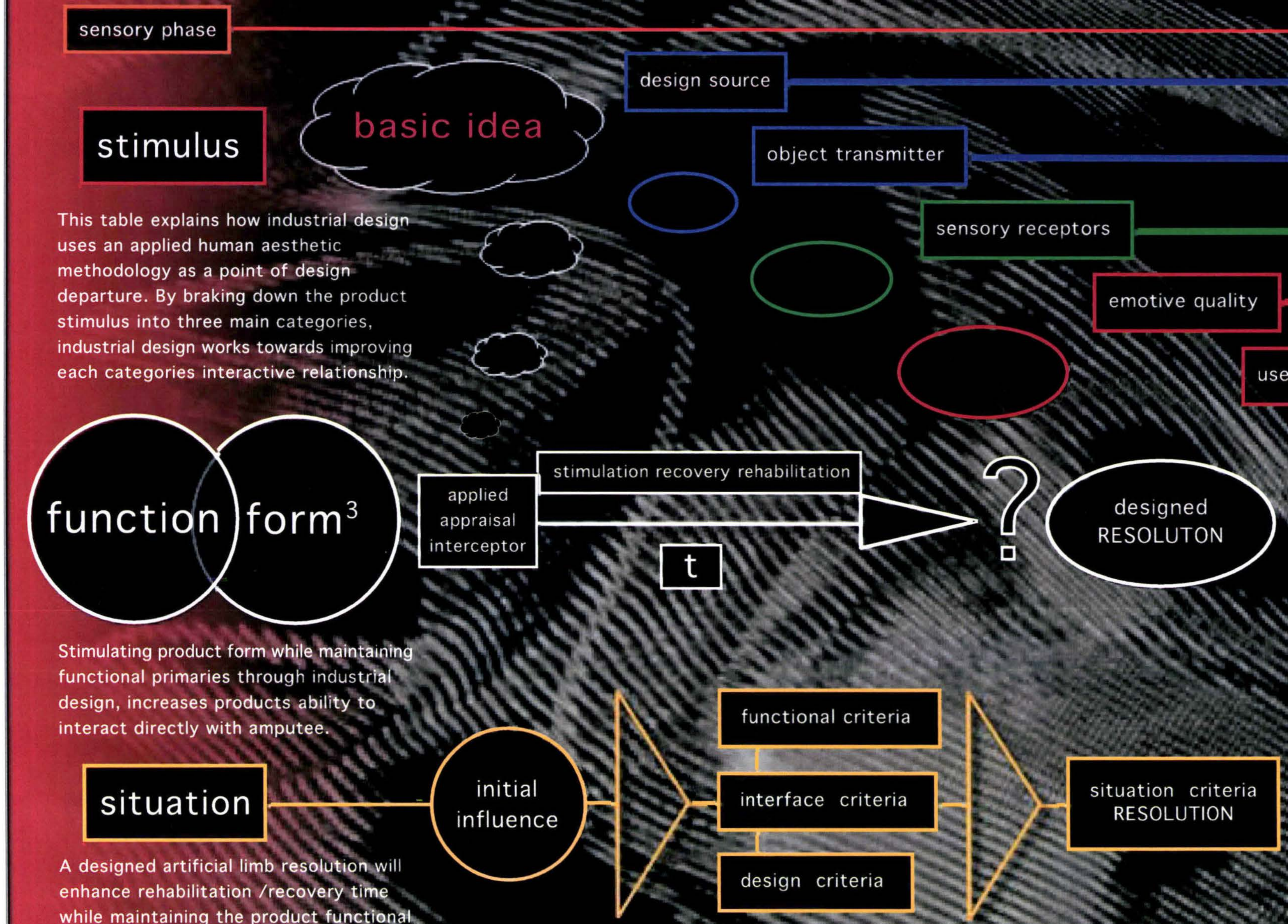
fig 83

to hold while writing, and it has the ability to biodegrade upon disposal. These designed functional results are achieved using exo-product architecture. There is also the visual aesthetic to take into consideration. Its unique form is identifiable as a specific brand, which is important in any market.

The product in (fig 81) is an exo-structure design that represents a term or concept called bio-metamorphic design. The aim of this product's exo-architecture or form is that of replicating a natural form (in this case that of a wood beatle), while still maintaining a functional criteria objective. This product is a chainsaw, it has all the functional criteria required to do its product aim, to cut wood. This is a form that is visually unique but initially unidentifiable. This result is achieved through exo-architecture design.

The chair shown in (fig 82) uses exo-architectural design to provide a pleasing visual aesthetic while also producing a pleasing and functionally emotive response when being used. Should the concept of exo-product architecture provide positive visual emotive qualities as well as fulfilling the functional criteria? Can this holistic design approach successfully achieve both function and form in a product's attributes? The artificial limb (fig 83) incorporates this holistic approach in its design objective, which is to provide a balance between function and designed form.

The following tables (51-59) show in graphic form the industrial design development process for the transtibial artificial limb.



sensory phase

stimulus

basic idea

design source

object transmitter

sensory receptors

emotive quality

user interaction/reaction

This table explains how industrial design uses an applied human aesthetic methodology as a point of design departure. By braking down the product stimulus into three main categories, industrial design works towards improving each categories interactive relationship.

function form^3

applied appraisal interceptor

stimulation recovery rehabilitation

t

?

designed RESOLUTON

Stimulating product form while maintaining functional primaries through industrial design, increases products ability to interact directly with amputee.

situation

initial influence

functional criteria

interface criteria

design criteria

situation criteria RESOLUTION

A designed artificial limb resolution will enhance rehabilitation /recovery time while maintaining the product functional primaries.

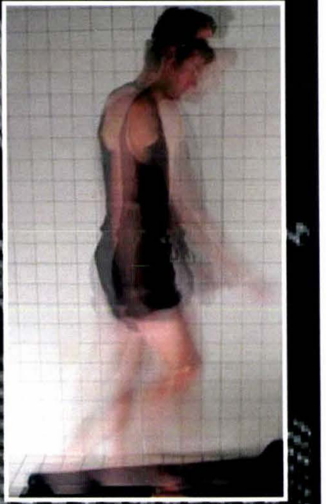
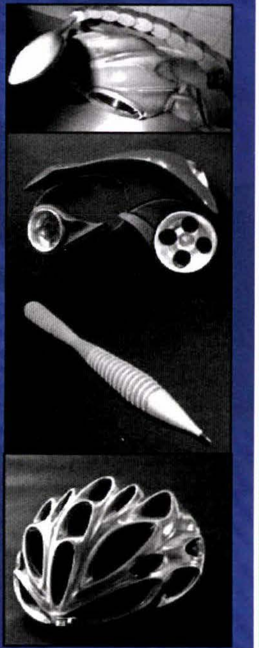


table 51

industrial design: artificial limb product design methodology

who would want it?
why would they want it?
what is it they want?

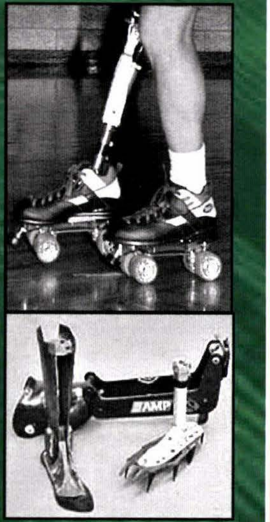
This table represents product interactive relationships and their desired communication. The stimulus factor is divided into three categories; wow, behavioural and reflective. The wow factor represents initial product aesthetic reaction. The behavioural factor identifies prerequisite functional primaries and the corresponding visual aesthetic. The reflective factor suggests the product's industrial design approach.



product design
- gothic influences
- technological influences

designed product
- visual appreciation
- self fulfillment

wow factor



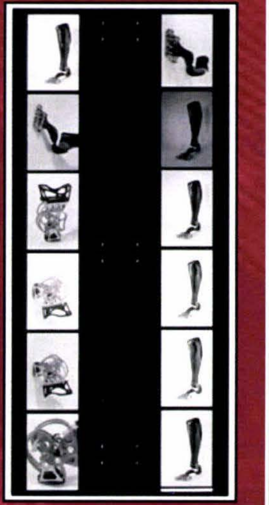
balance
- form/functon

ergonomics
- customisation

performance
- functional criteria

physical
- utility attributes

behavioural factor



sociology
- branding

look-feel
- interactive

cultural
- personal identity

sociometry
- group relationships

reflective factor

table 52

9.3

product trend map

product design

- gothic influences

exo-skeletal structural architecture

product arousal
wow factor

designed product

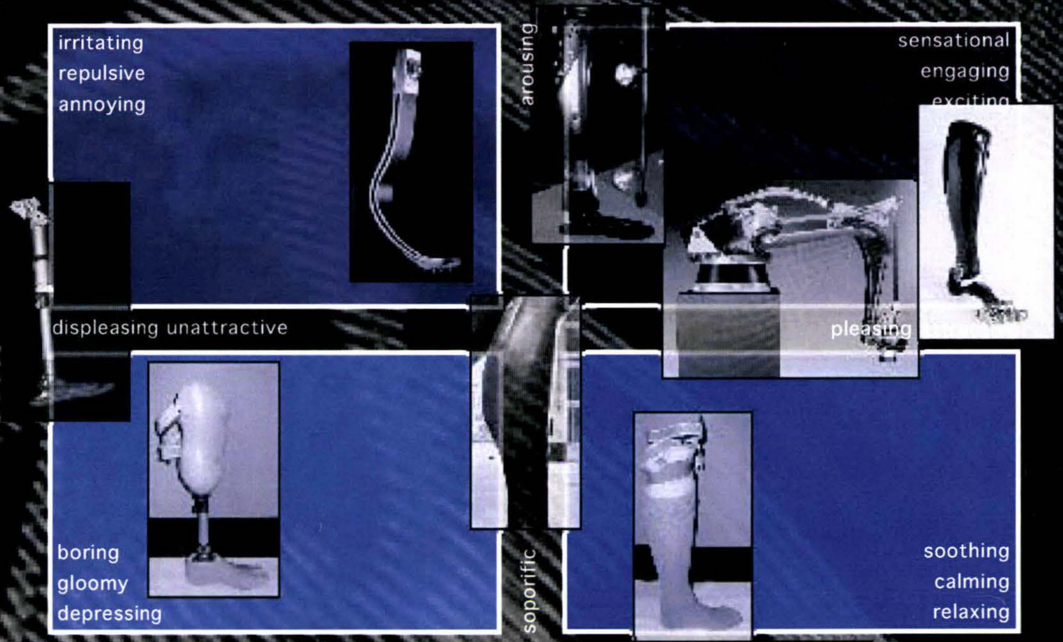
- visual appreciation

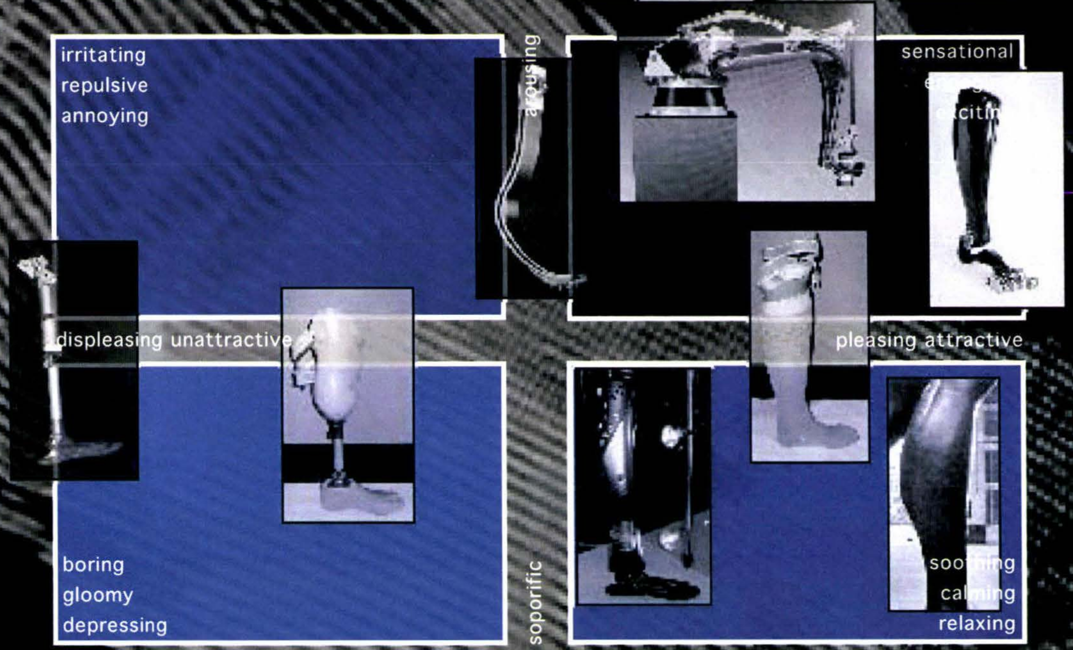
iconic identity

product representation

natural form replication

table 53





product trend map

product design

- technological influences

composite material lamination combinations

product manufacturing processes

product arousal
wow factor

designed product

- self fulfillment

interface interaction

utility celebration

motive interaction

table 54

product trend map

balance

- form^{3}=function

sum of function and form

product arousal behavioural factor

ergonomics

- customisation

individual user requirements and preferences

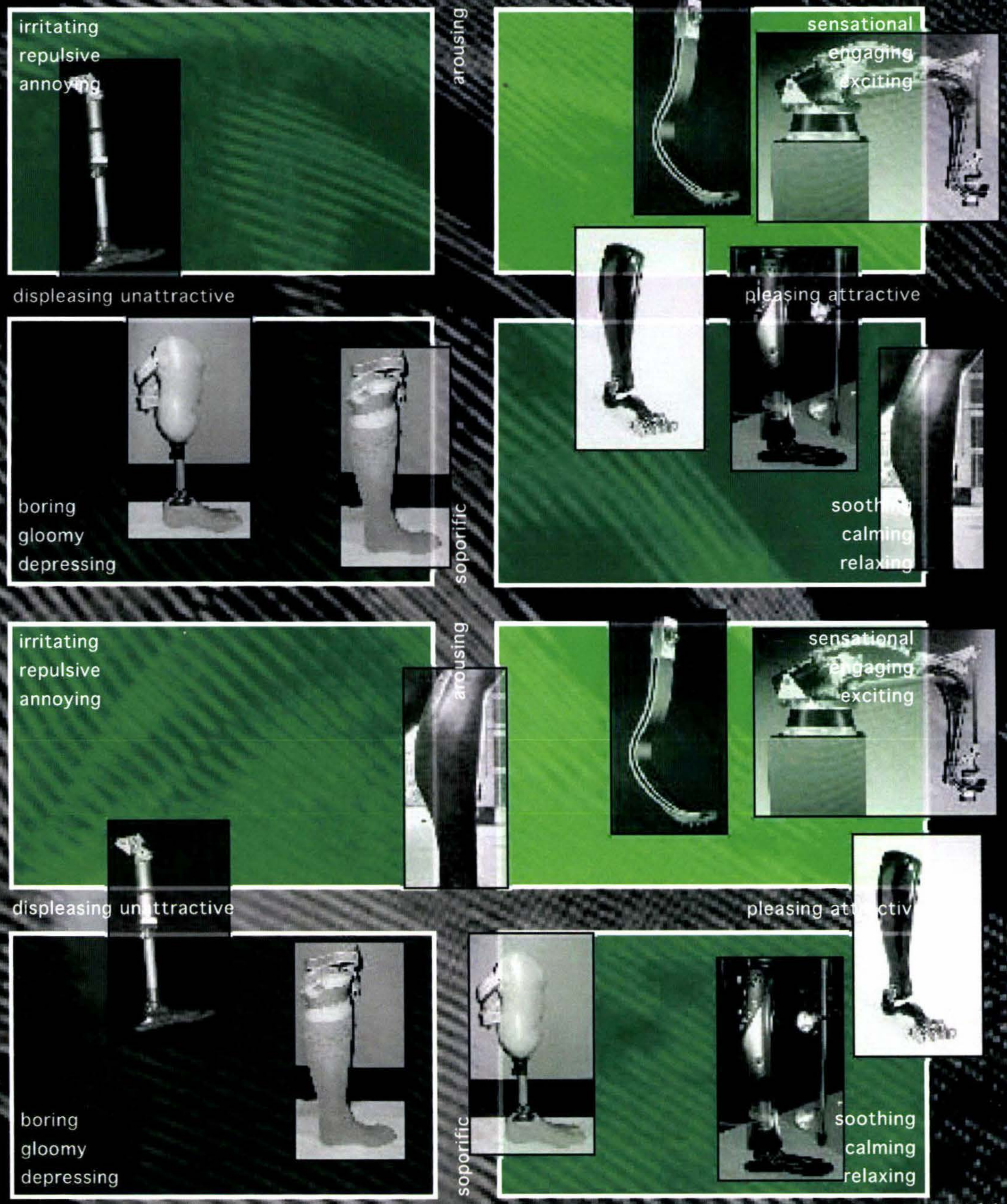


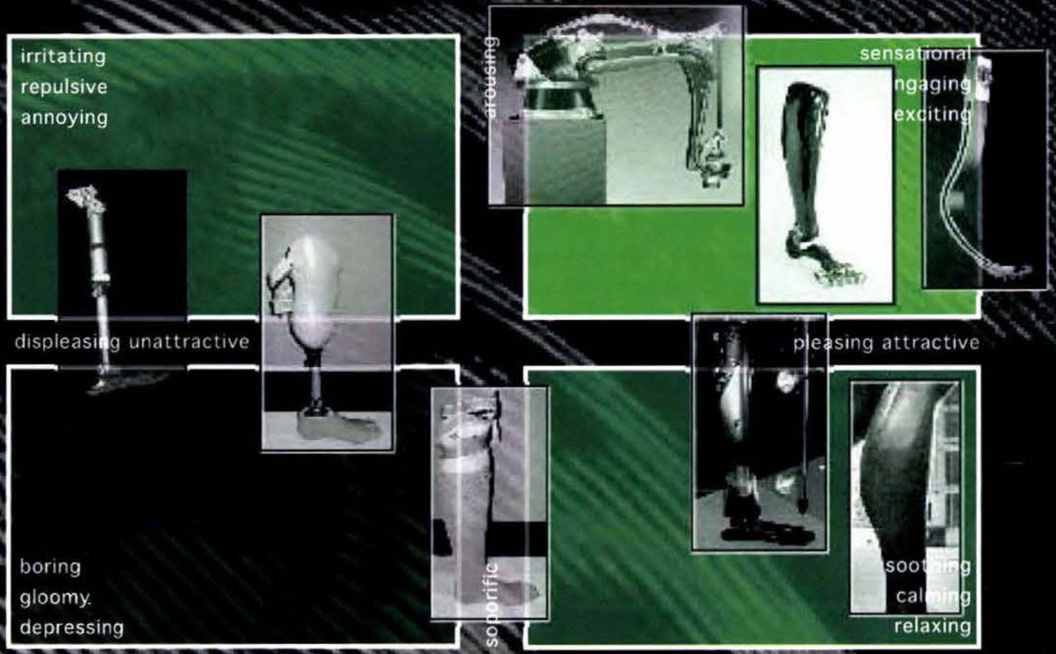
table 55

product trend map

performance

- functional criteria

functional objective criteria and preferences



product arousal
behavioural factor

physical

- utility attributes

lifestyle resistant

user independence

table 56

product trend map

look-feel

- interactive

interfacing systems and controls

environment performance

product arousal reflective factor

sociology

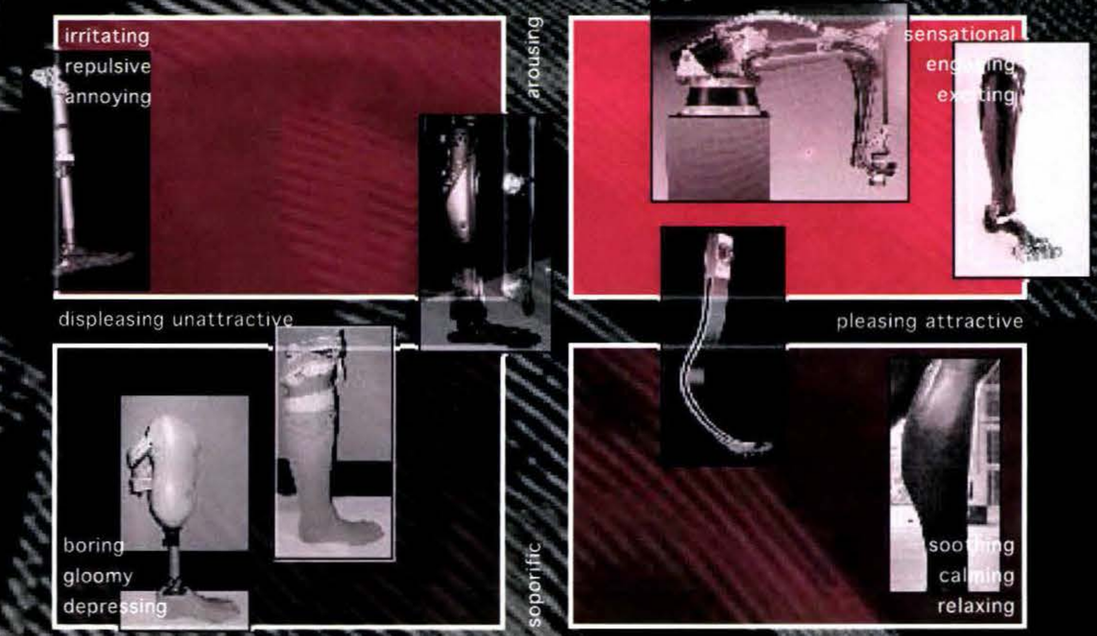
- branding

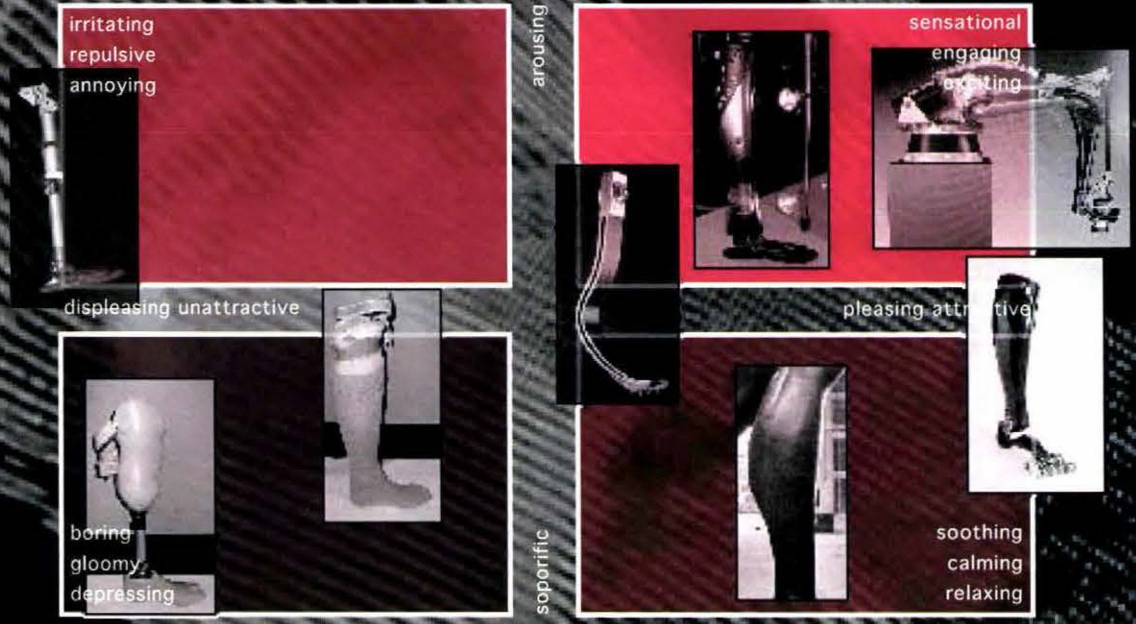
visual image identity

recognised designed form

functional aesthetic

table 57





product trend map

cultural

- personal identity

individual ethnic identity

product arousal reflective factor

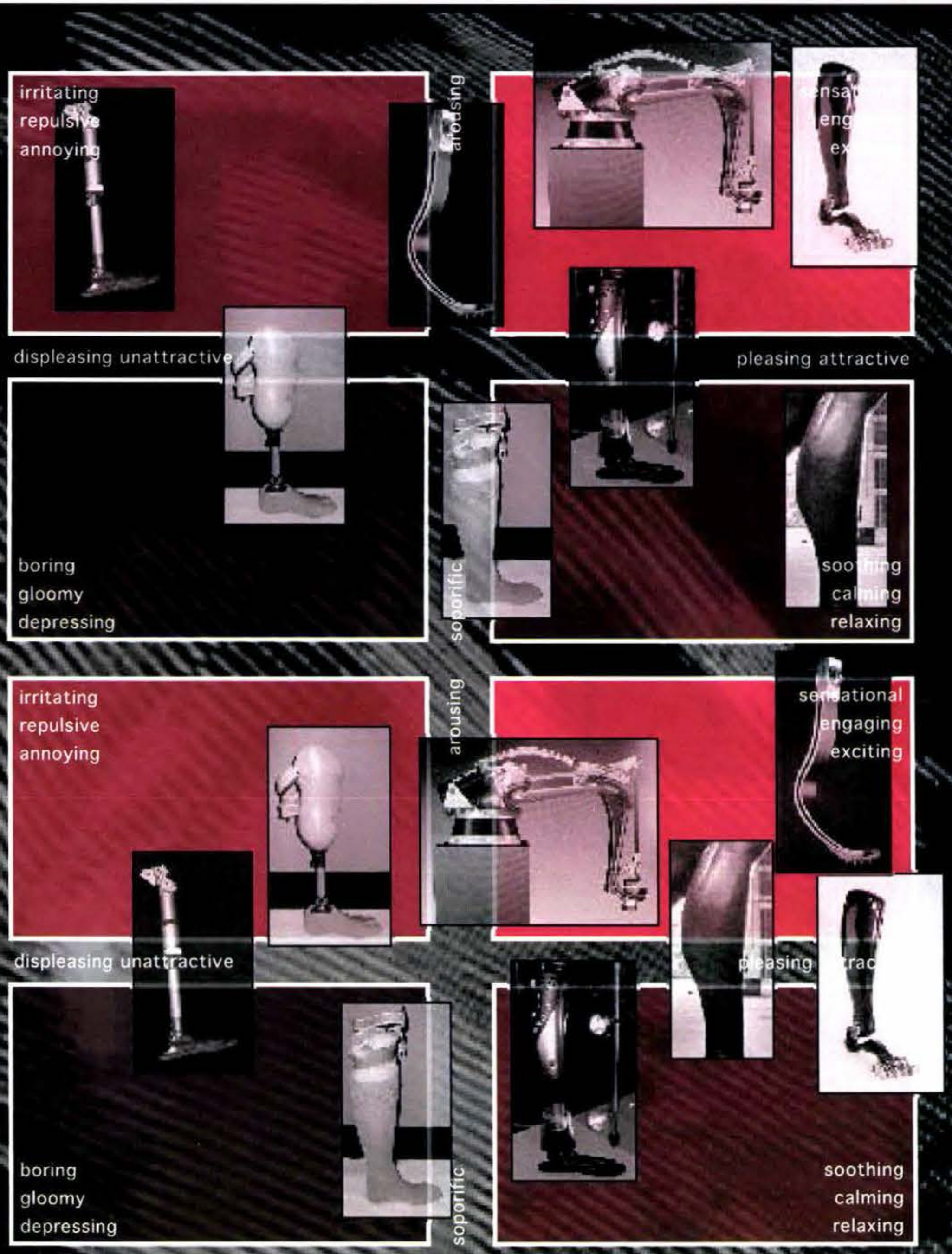
sociometry

- group relationships

interelationships

visual communication

table 58



This table identifies present and future artificial limb research development and design trend direction.

Current trends suggest software integrated mechanical design direction. Future trends direction may aim towards biological cloning reproduction.

9.4


Britten motorcycles designs custom artificial limbs for extreme sports


Otto Bock myoelectric nerve impulse arm developed


carbon laminated artificial limbs applied to animals with limb amputations

robotic technology develops creative functional solutions for unconventional purposes


robotic enhancement exo skeleton successfully trialled on the moon


Kuka robotic technology develops exo skeleton human enhancement for off world exploration


cyborg bio-robotic technology developed


exo skeleton designed suit used on mars during martian exploration


genetically enhanced and modified human clones with shortened life spans developed and used for labour purposes


genetically grown clones used for spare parts for the wealthy

transtibial artificial limb

2001


Otto Bock C sprint leg developed


Otto Bock robotic Cleg developed

2010


artificial limb product designed range launched


transtibial amputee crosses finish line in 100m sprint in sub 10 second time using Otto Bock c-sprint artificial limb 2020 Paris Para Olympics

2025


modular artificial limb component system designed for 3rd world mass production application


cloned human leg grown in China


scientists grow a full set of bones for a leg while trying to strengthen the structure

2040


cloned human leg grown on the back of a bio-engineered lab rat

2050

table 59

industrial design: artificial limb product forecasting timeline

9.5

exotibius design criteria

The design criteria for the exotibius transtibial artificial limb are:

- The exo-skeleton is designed to replicate the natural form of the missing limb(s);
- The artificial limb co-exists with current state of the art modular prosthetic products;
- Replicates a natural kinetic return during walking and jogging phases;
- Uses current artificial limb fitting and production process;
- Uses a resin/material composite vacuum injection lamination process;
- Incorporates carbon fibre, Kelvar and Nitinol alloy mesh laminated exo-construction;
- Incorporates a Teflon outer coating; and
- Allows for skin stocking covering.


figs 84


figs 85


figs 86


figs 87


figs 88


figs 8


fig


figs 92

fig 107

applied human aesthetic in artificial limb design
transtibial artificial limb
design development prototyping

masters industrial design development study

10.0

exotibius concept design development

This study required the design and development of a working (unfitted) transtibial artificial limb (figs 93-96). The following sections outline the concept design development process. These sections are in chronological order, (from the initial concept through to the final designed form). This was done to assist with the concept development including ongoing refinement and evaluation, during this stage of the study.

The first design was based on a modular type leg system. It contained little humanistic form but fitted the basic design criteria. The next stage of the concept design process was a detailed myographic study of the transtibial region to gain an understanding of the localised muscled groups, their form, and to a lesser extent, their function. The final stage consisted of refining the exotibius design into a workable prototype.


fig 93


fig 94


fig 95


fig 96


fig 97

Fig 97 shows the range of prototyping produced during this study. A natural volume and form is clearly recognisable, the intention was to refine the visual aesthetic of the prototype while using the lamination process.

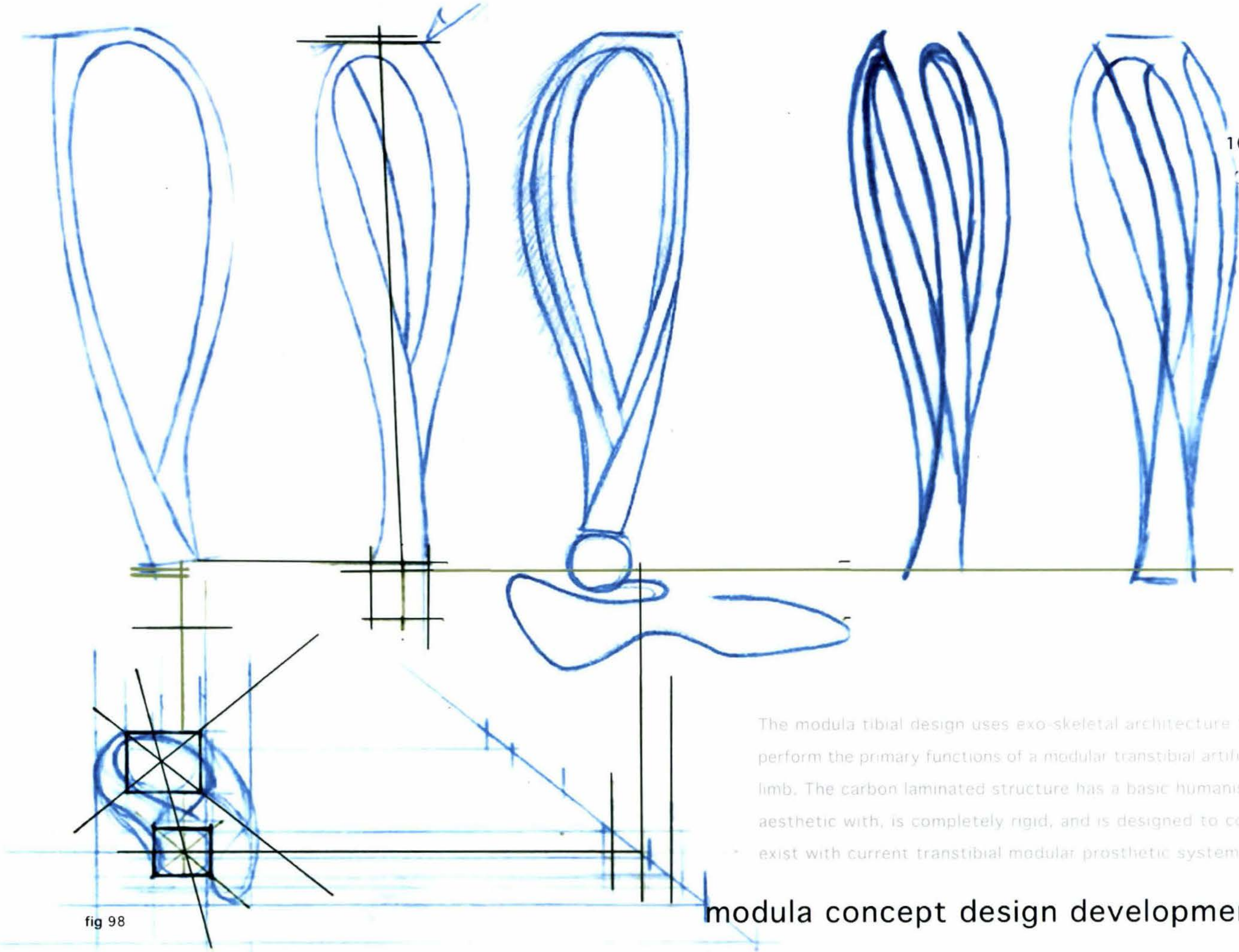
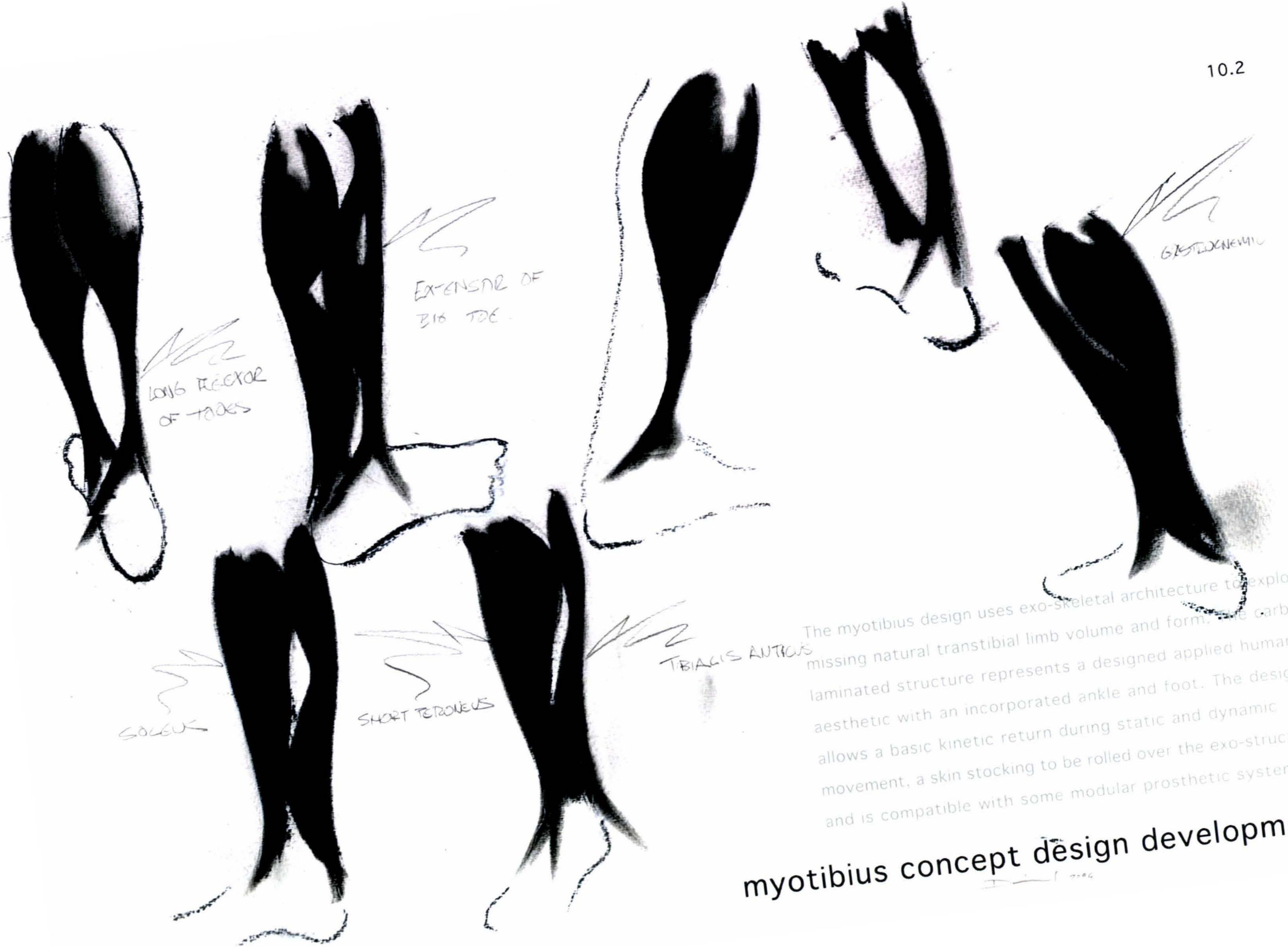


fig 98

The modula tibial design uses exo-skeletal architecture to perform the primary functions of a modular transtibial artificial limb. The carbon laminated structure has a basic humanistic aesthetic with, is completely rigid, and is designed to co-exist with current transtibial modular prosthetic systems.

modula concept design development

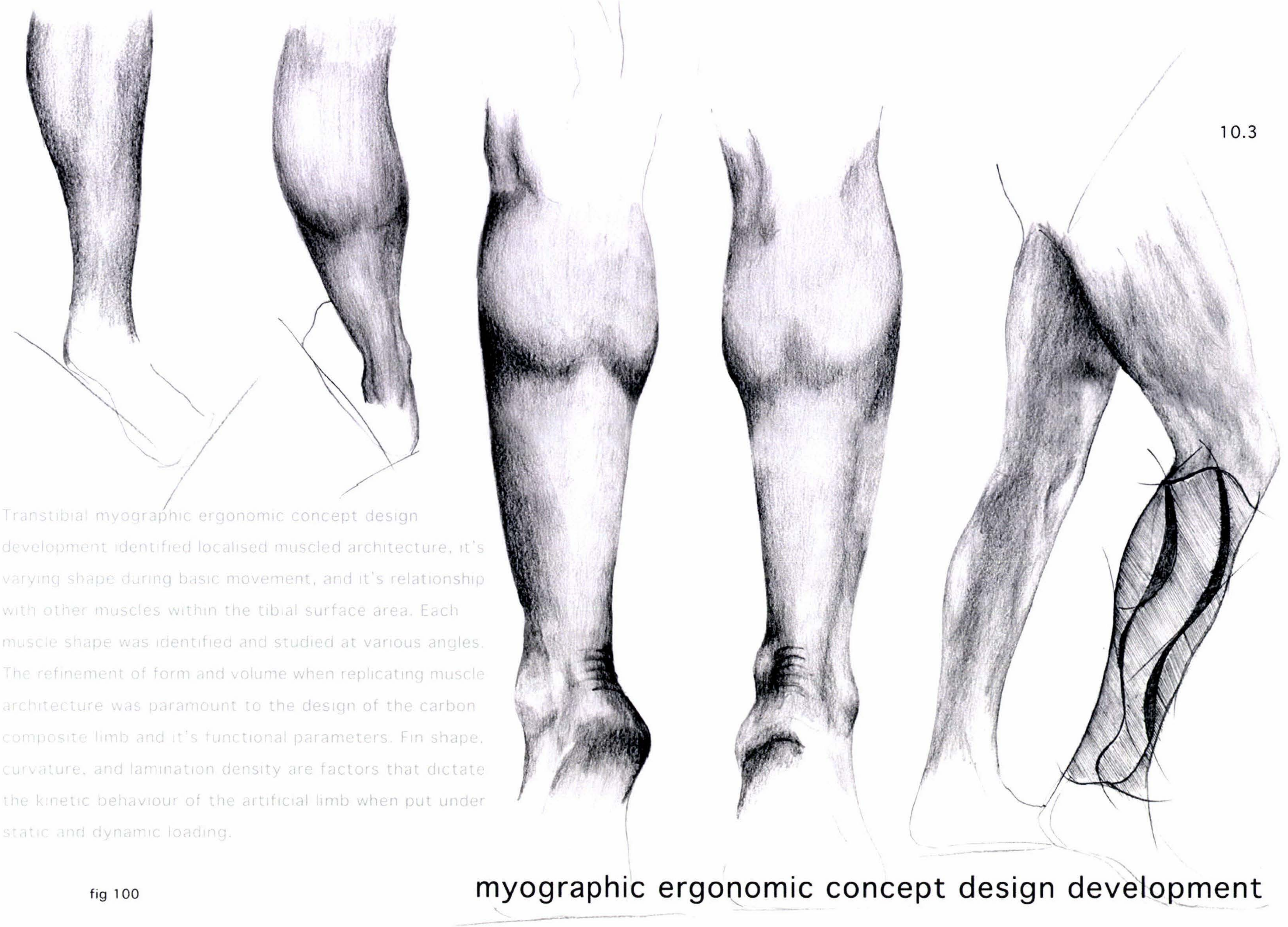


The myotibius design uses exo-skeletal architecture to explore missing natural transtibial limb volume and form. The carbon laminated structure represents a designed applied human aesthetic with an incorporated ankle and foot. The design allows a basic kinetic return during static and dynamic movement, a skin stocking to be rolled over the exo-structure, and is compatible with some modular prosthetic systems.

myotibius concept design development

plate 1

myotibius concept design development



Transtibial myographic ergonomic concept design development identified localised muscled architecture, it's varying shape during basic movement, and it's relationship with other muscles within the tibial surface area. Each muscle shape was identified and studied at various angles. The refinement of form and volume when replicating muscle architecture was paramount to the design of the carbon composite limb and it's functional parameters. Fin shape, curvature, and lamination density are factors that dictate the kinetic behaviour of the artificial limb when put under static and dynamic loading.

fig 100

myographic ergonomic concept design development

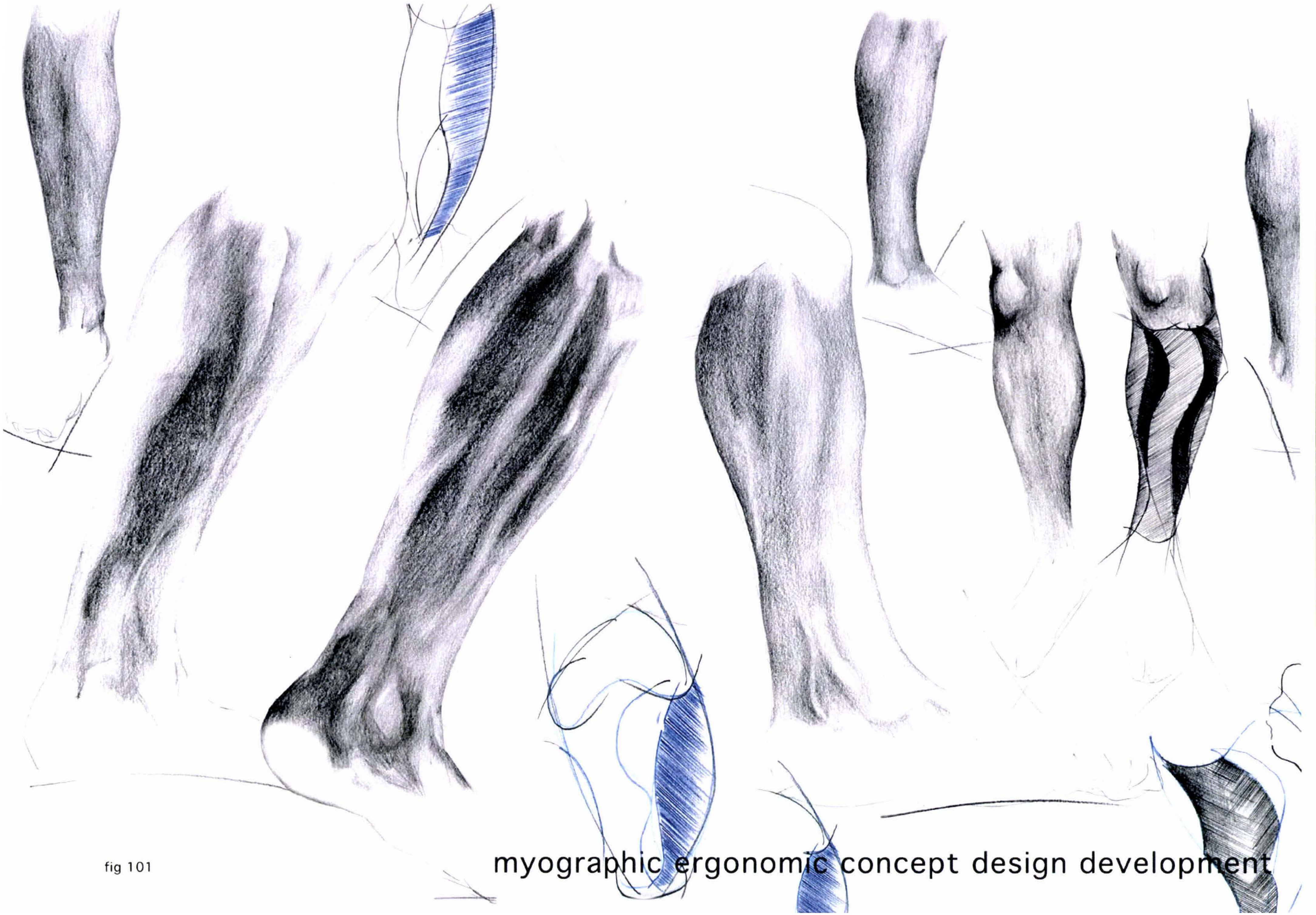


fig 101

myographic ergonomic concept design development

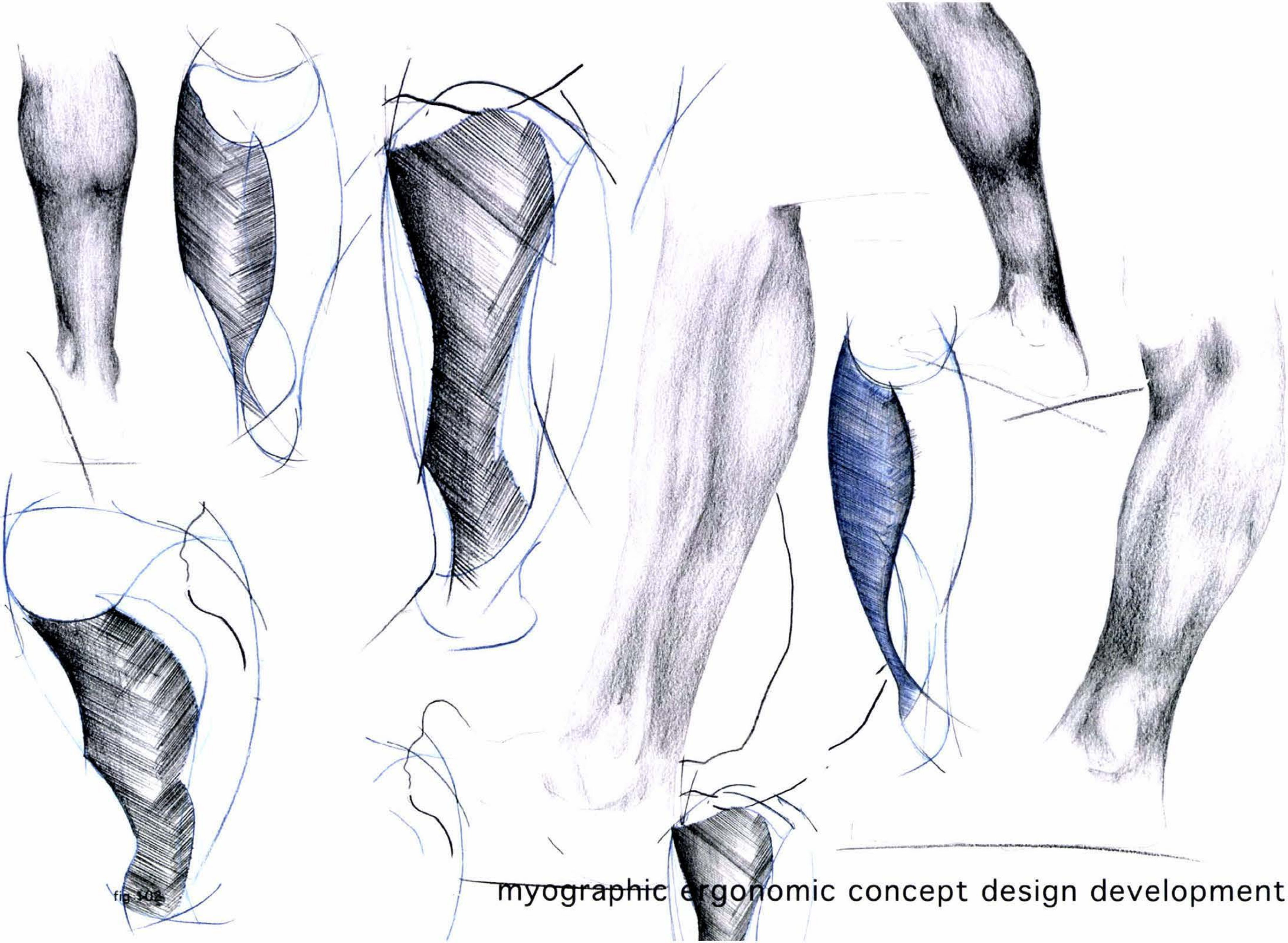


fig 102

myographic ergonomic concept design development

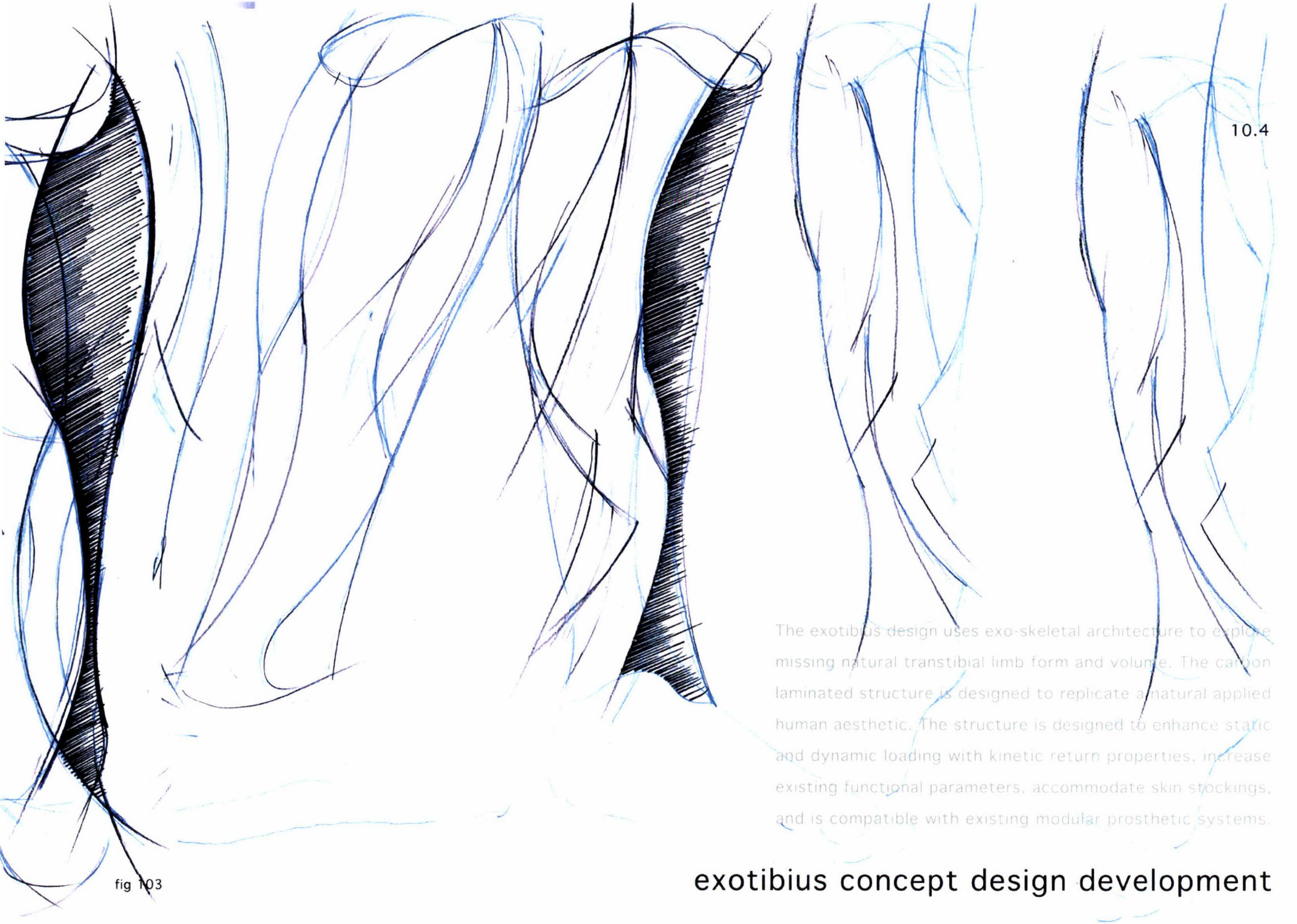


fig 103

The exotibius design uses exo-skeletal architecture to explore missing natural transtibial limb form and volume. The carbon laminated structure is designed to replicate a natural applied human aesthetic. The structure is designed to enhance static and dynamic loading with kinetic return properties, increase existing functional parameters, accommodate skin stockings, and is compatible with existing modular prosthetic systems.

exotibius concept design development

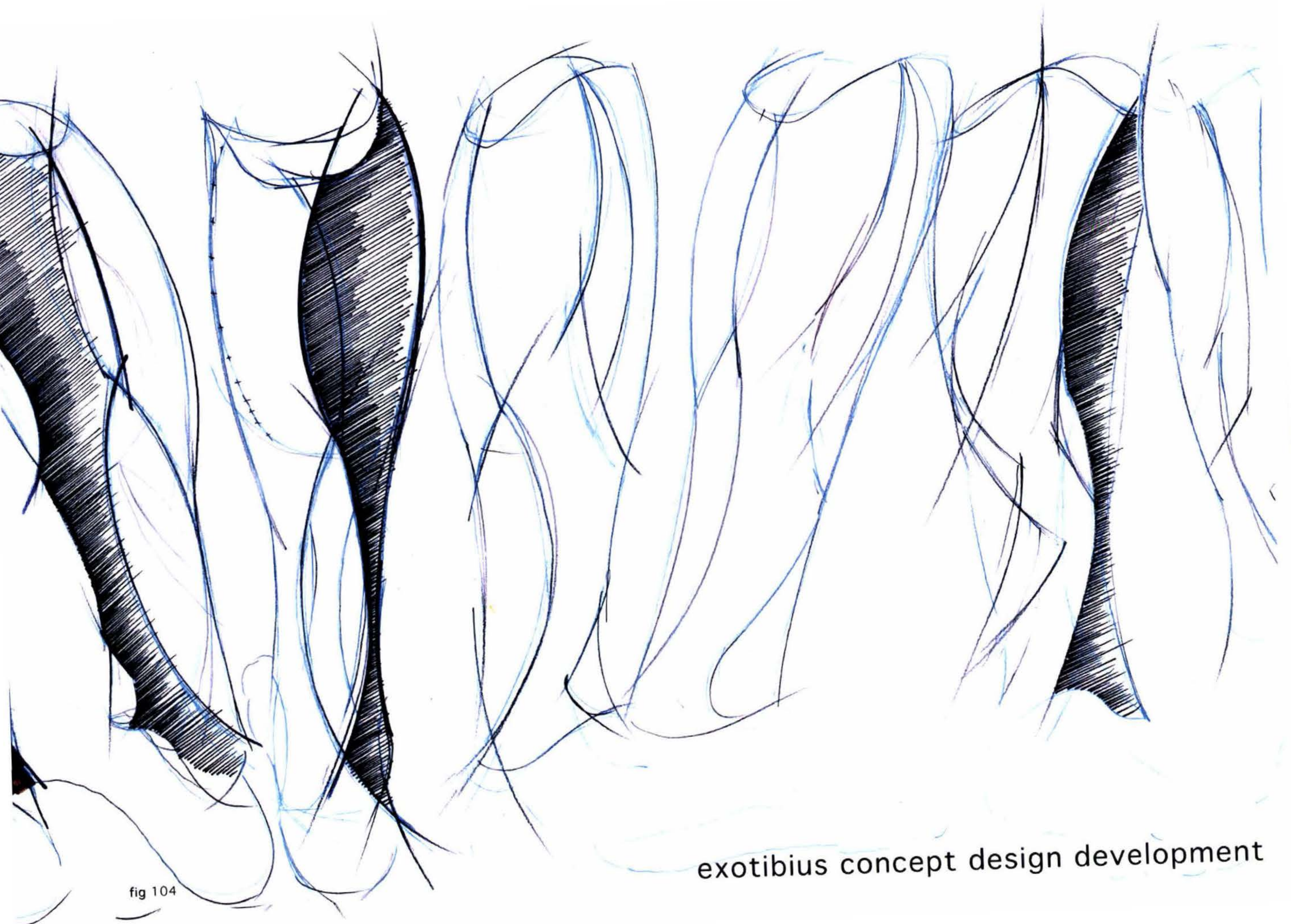


fig 104

exotibius concept design development

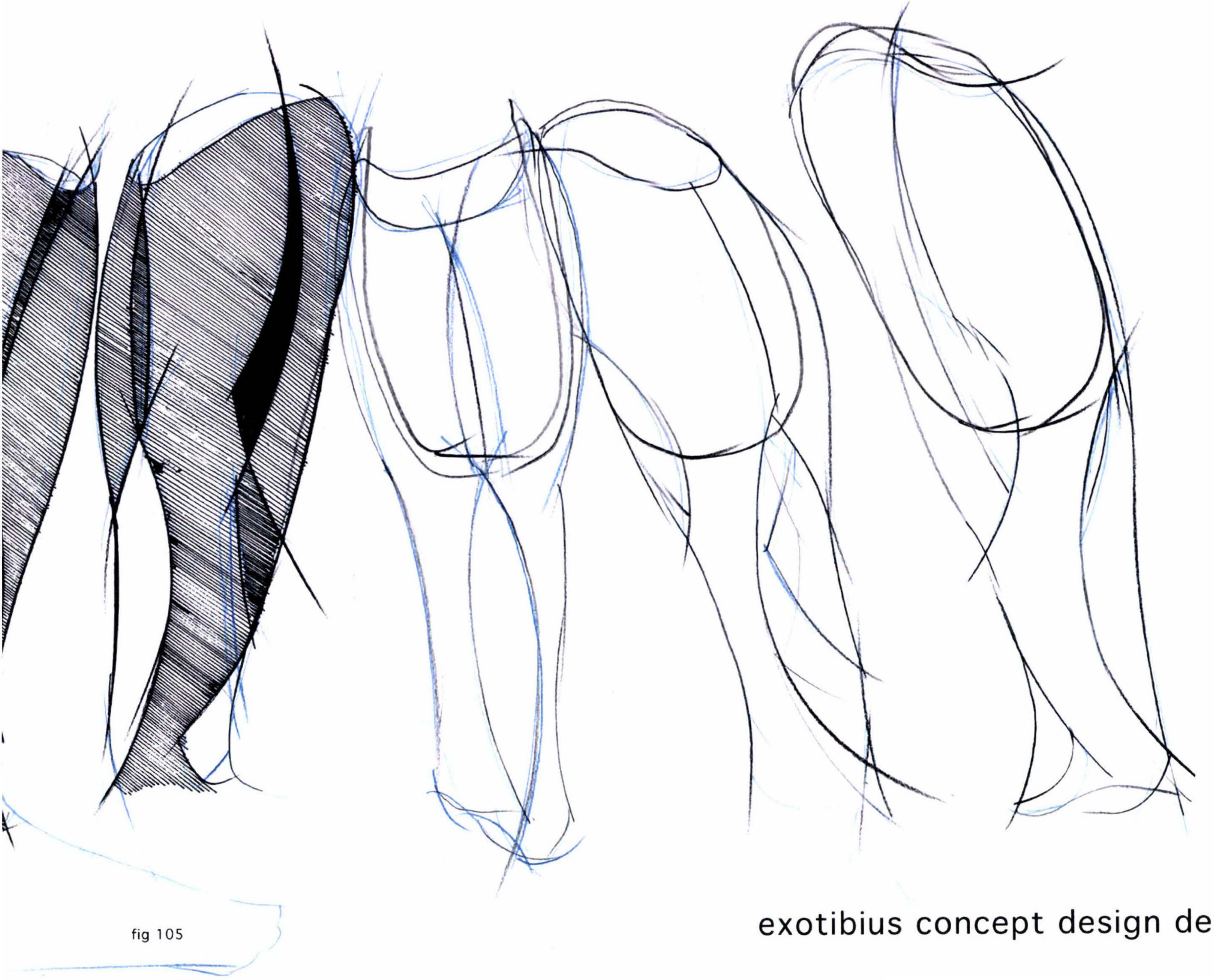


fig 105

exotibius concept design development

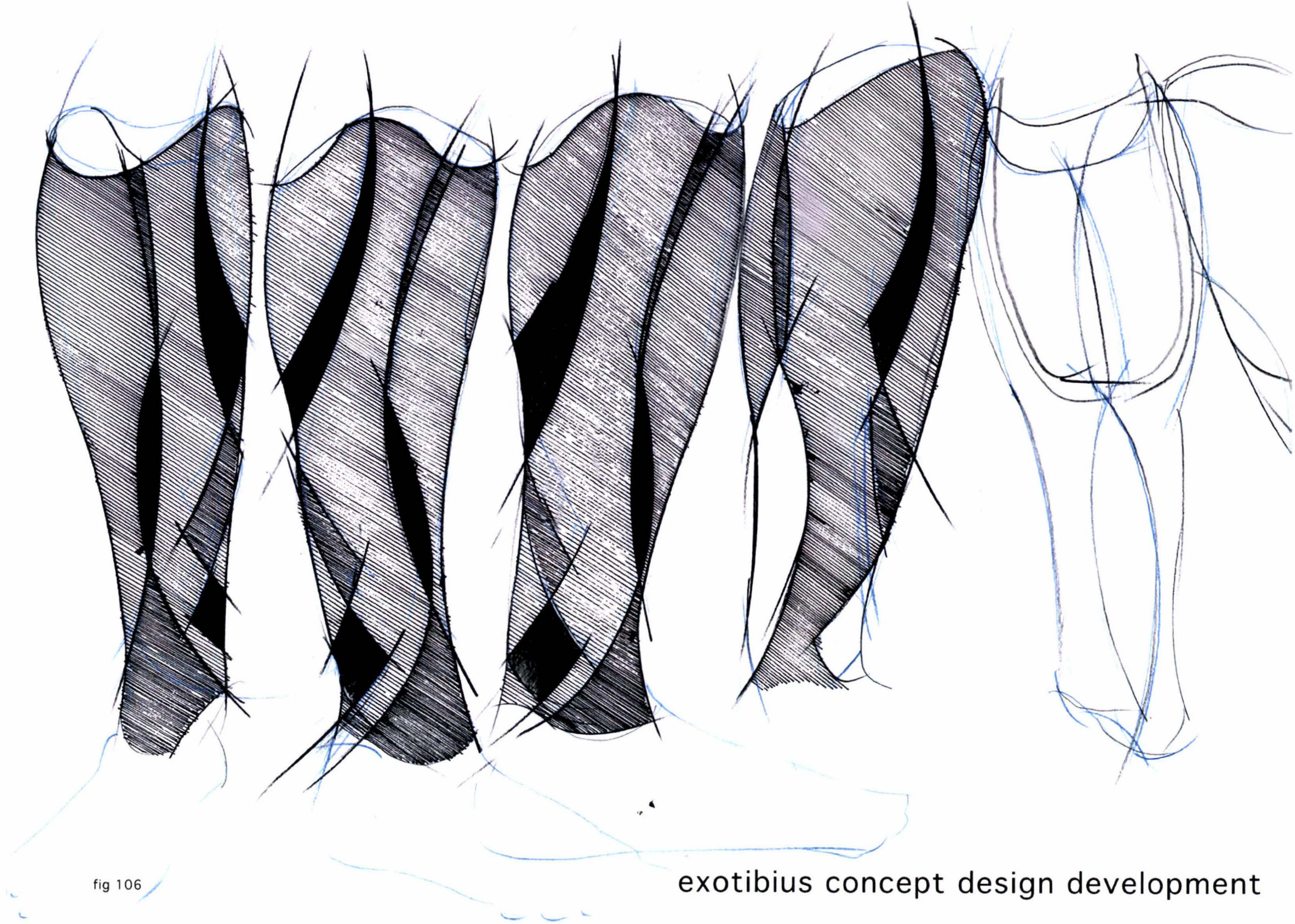


fig 106

exotibius concept design development

plate 2

exotibius transtibial artificial limb

plate 3

exotibius transtibial artificial limb

10.5

mould prototyping
transtibial plaster molding

This section discusses the fabrication process of the transtibial moulds used during the prototyping of the exo-shell.

To achieve the design development objectives for this study, it was necessary to get a range of leg sizes and shapes to apply the exo-shell concept design. Transtibial moulds were fabricated from plaster negative moulds taken from four leg models. Three females and one male were used. The four leg models ranged in size from a 55 percentile female, a 80 percentile female, a 97 percentile male, and a 99 percentile female.

Using quick set plaster, negative leg moulds were taken from both the front and back of the legs (fig 107). The quick set plaster allowed the moulds to be removed in a relatively short time about 15-20 minutes. This minimised any possible distortion in the moulds created by the leg models moving while the plaster negatives were still wet. The final negative shells were of very good quality and reflected successfully the modeled form.


fig 107


fig 108


fig 109


fig 110

The next stage involved creating two positive transtibial leg moulds, front and back (figs 109/110). Setting quick cast plaster into the core of the negative moulds (fig 107) and using plywood strips running vertically up the shell provided a rigid form. Once set, the two halves (figs 108/109) were joined together to form a completed transtibial positive leg mould. The alignment of the two halves was critical when joining them together. Markers were place at certain points along the mould for alignment purposes. Any misalignment at this stage would create a distorted finished form.

Once the halves were aligned and the moulds attached together, the next stage consisted of separating the ankle mould from the initial form (fig 113). This part is used to produce the ankle block form for the final prototypes (fig 111). A hole large enough to fit the transtibial stump socket was formed in the top of the mould (fig 112), once aligned the stump socket was then casted in place.


fig 111


fig 112

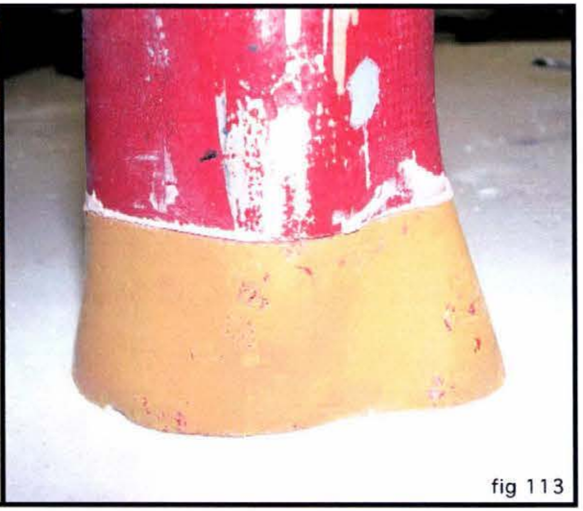


fig 113

All the four pieces of the positive mould were fitted together successfully, the completed transtibial mould was sanded, prepped and primed for multiple layers of top coat lacquer. A resin layer should have been applied (fig 114) after the mould had been sanded up.

The final stage of the transtibial mould production consisted covering the outer mould with a high gloss lacquer paint and polishing. Initially nine layers of top coat were applied to the form for protection. The layers of paint were given three days to dry and bond to the surface. A clear lacquer application was then applied, cured and then polished. The final result while looking fantastic (figs 115-117) proved to be less successful during the lprototype amination process.

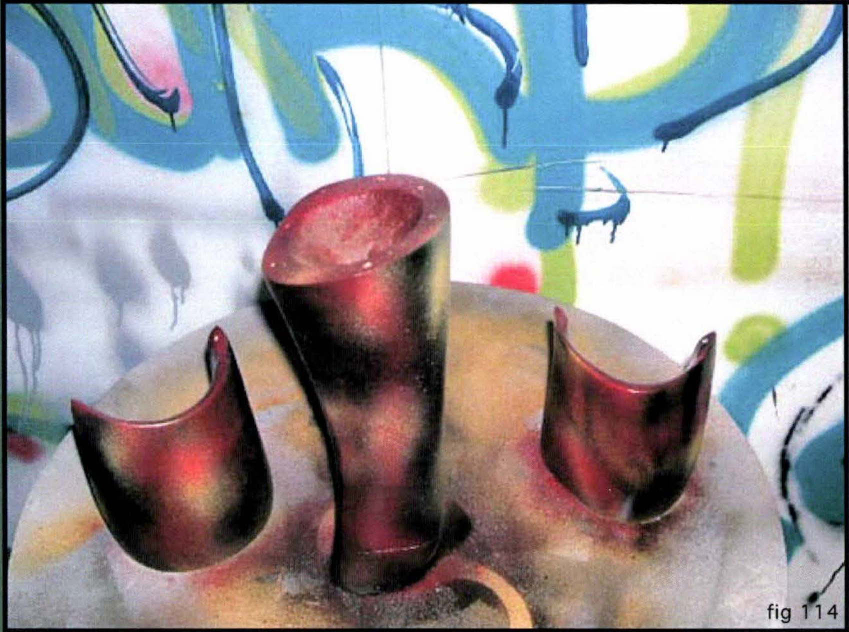


fig 114

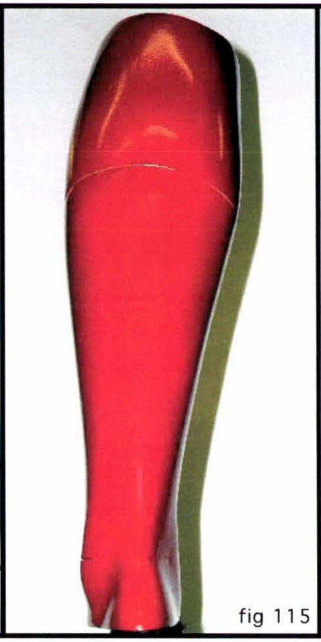


fig 115

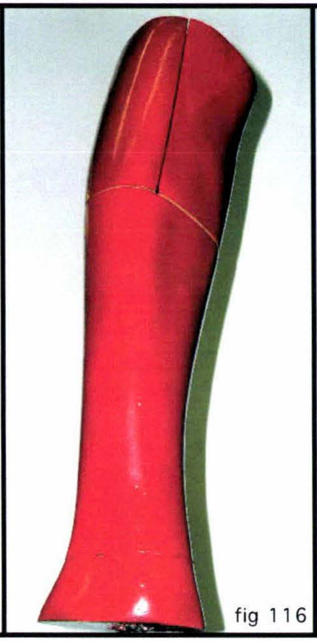


fig 116

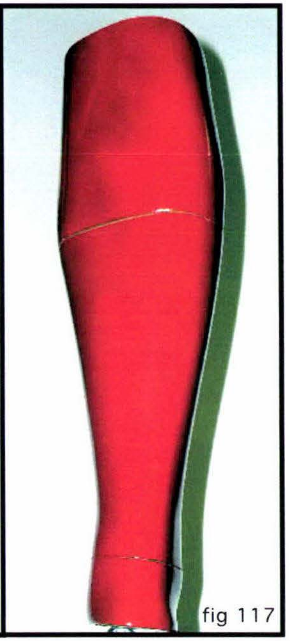


fig 117

10.6

composite materials

Composite materials have been classified in many ways. The most common classificiations to date have been identified by their purpose and the respective functional parameters. There are three main groups or broad classifications of composite materials: natural composite materials, microcomposite materials and macrocomposite materials. Most naturally occurring materials derive their superior properties from a combination of two main components: the degree of strength they can achieve and their enormous flexibility. The voluntary muscles in the human body have these qualities. Stiff fibres are aligned in such a way as to provide maximum stiffness in the direction of high loads and are also able to slide past each other as the interface tissue are very flexible. Another example of a natural composite is the unique property found in bamboo. Microscropic examination of bamboo reveals a fibrillar string structure, which becomes apparent when broken. It is often referred to as nature's 'fibre glass'. Bamboo is constructed from uni-directional fibres which are equivilant to alluminium in weight but signficantly stronger.

One example of an extreme use of bamboo is the scaffolding surrounding the construction of high rise buildings in Hong Kong 2004 (figs 118-120).

fig 118

fig 119

fig 120

10.7

composite materials
swot analysis

The following tables list the strengths, weakness, opportunities and threats in materials currently used in the fabrication of artificial limbs.

Wood, leather and steel respectively are most affected by their ability to react to moisture.
Leather is the only material attributed hygiene issues.
Mild steel while heavy in weight is easily mended.
Aluminum is affected by salty environments.
Thermo plastic and Kevlar reacts to UV sunlight over a long period of time.
Glass, carbon and kevlar produce products that require servicing and maintenance and have a limited lifespan.

table 60

materials	strengths	weaknesses
wood	- biocompatible - available - simple tools - easily repaired locally	- deteriorates in the wet - prone to warping - heavy
leather	- moulds easily - generally repairable - biocompatible - easily repaired locally	- deteriorates quickly - deforms - requires reinforcements - hygiene problems
mild steel	- easily mended - good strength - generally available - easy to repair locally	- corrodes - fatigues - heavy
aluminium	- lightweight - generally available - easily *melded*	- corrodes with salt - fatigues with use - *not* easily welded
glass fibre lamination	- current accepted technology - cosmetic options - water resistant - strength/durability	- (carcinogenic) worker safety - difficult to repair - resins have limited shelf life
thermoplastics foam	- lightweight - water resistant - strong - recyclable	- difficult to repair - prone to structural weakness with ultra violet/sunlight
carbon/Kevlar composite alloy mesh lamination	- existing production technology - structurally very strong - water resistant - cosmetic options - large volume production - easily customised	- (carcinogenic) worker safety - difficult to repair - resins have limited shelf-life

composite materials
swot analysis

table 61

materials	opportunities	threats
wood	- laminated woods available - accessible to developing countries - recyclable - customisable - easily obtainable	- depleting resources - prone to local environmental conditions
leather	- various leathers available - accessible to developing countries - recyclable	- prone to local environmental conditions - requires specalist tools
mild steel	- recyclable - accessible to developing countries - easily serviced	- prone to local environmental conditions - requires welding
aluminium	- recyclable - resistant to environment - easily worked	- prone to local environmental conditions - hard to obtain in developing countries
glass fibre lamination	- resistant to enviornment - strong/durable - adaptable product	- prone to hot environmental conditions - specialist materials required
thermoplastics foam	- recyclable - resistance to enviornment - adaptable product	- prone to hot environmental conditions - hard to obtain materials
carbon/Kevlar composite alloy mesh lamination	- resistant to environment - adaptable product - strong/durable	- hard to fix/service - hard to obtain materials - hard to dispose of

10.8

composite materials product & application

The lamination materials used for this project were employed because of their unique shape, moulding properties, their ability to hold the shape once formed, and their lightweight and structurally sound properties. The objective was to use state of the art materials that are readily available and used in the current prosthetic market, as well as incorporating other materials that are less well known but are used in composite laminations in other industries. They were then catagorised into two groups based on their individual properties and the products' design criteria.

The primary material group for this study consisted of the following:

- A range Carbon fibre fabrics and socks (figs 121/124) were used during prototyping. The fabric was used during the hand lay lamination process, the sock was used for the final form prototypes. Carbon sock is commonly used in the prosthetic industry due to it's unique structure.


fig 121


fig 122

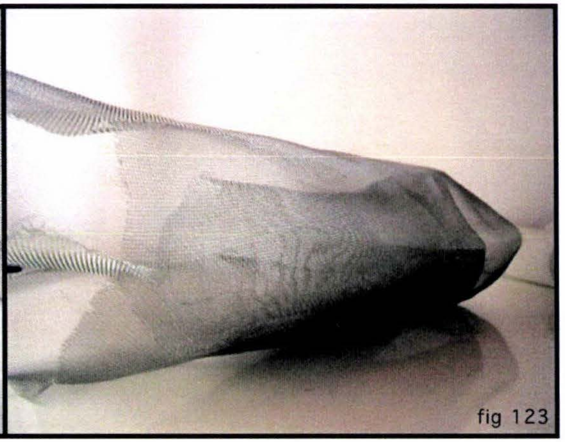


fig 123

- Alloy mesh (fig 123) is not currently used in the prosthetic industry, it is however common in the cycling industry where it is used in the construction of composite bicycle frames. It places extra rigidity into the structural architecture of any composite component it is laminated into while introducing minimal weight.

- Memory foam (fig 127) is used in horse saddle pads and bed mattresses. This elastic viscous properties of the foam has memory, is breathable, has pressure dispersal and temperature control property attributes, it is not currently used in the prosthetic industry.

- Cuban fibre fabric (fig 126) is not currently found in the prosthetic industry but is commonly used as sail cloth in the marine industry. It is a very fine, lightweight fabric that is also structurally very strong with a teflon like finish.

A secondary material group consisted of the following materials:

- Texilium aluminised glass fabric (fig 122) is most commonly used to insulate pipes in air conditioning units. Its colouring adds a unique flavour to the range of laminating fabrics available. It has sound insulating properties but little structural significance.
- Carbon Kevlar hybrid and Kevlar fabric (fig 126). The hybrid fabric is commonly found in the marine and military industries. It is incredibly strong, impact resistant, and is used to make bulletproof vests. Kevlar fabric is used in the marine industry, commonly used in the fabrication of racing yacht hulls and components. Both fabrics will only be used during the prototyping stage if structural strength is required.


fig 124


fig 125


fig 126


fig 127

10.9

composite materials classifications

The following table lists a broad classification of composite materials.

types of composite material	- examples
natural composite	- wood - bone - bamboo - muscle and other tissue structure
micro composite	- metallic alloys - steels - thermoplastics - impact polystyrene - ABS - sheet moulding compounds - reinforced thermoplastics - glass fabric - carbon fabric - Kevlar fabric
macro composite	- galvanised steel - reinforced concrete beams - helicopter blades

Most bulk engineering materials are also combinations of two or more phases dispersed on a microscopic scale to obtain optimum properties. Natural materials and engineering materials are both microcomposites since their properties are the result of a very fine dispersion of layers. The strength and toughness of metallic alloys and thermo plastics are achieved by combining high strength phases and tough ductile phases. The composite idea can also be related to the macro scale. This is particulary relevant to engineering components consisting of two or more materials which combine to perform services that are superior to a single material. *Carbon fabric* and memory alloy mesh is one example of such a combination.

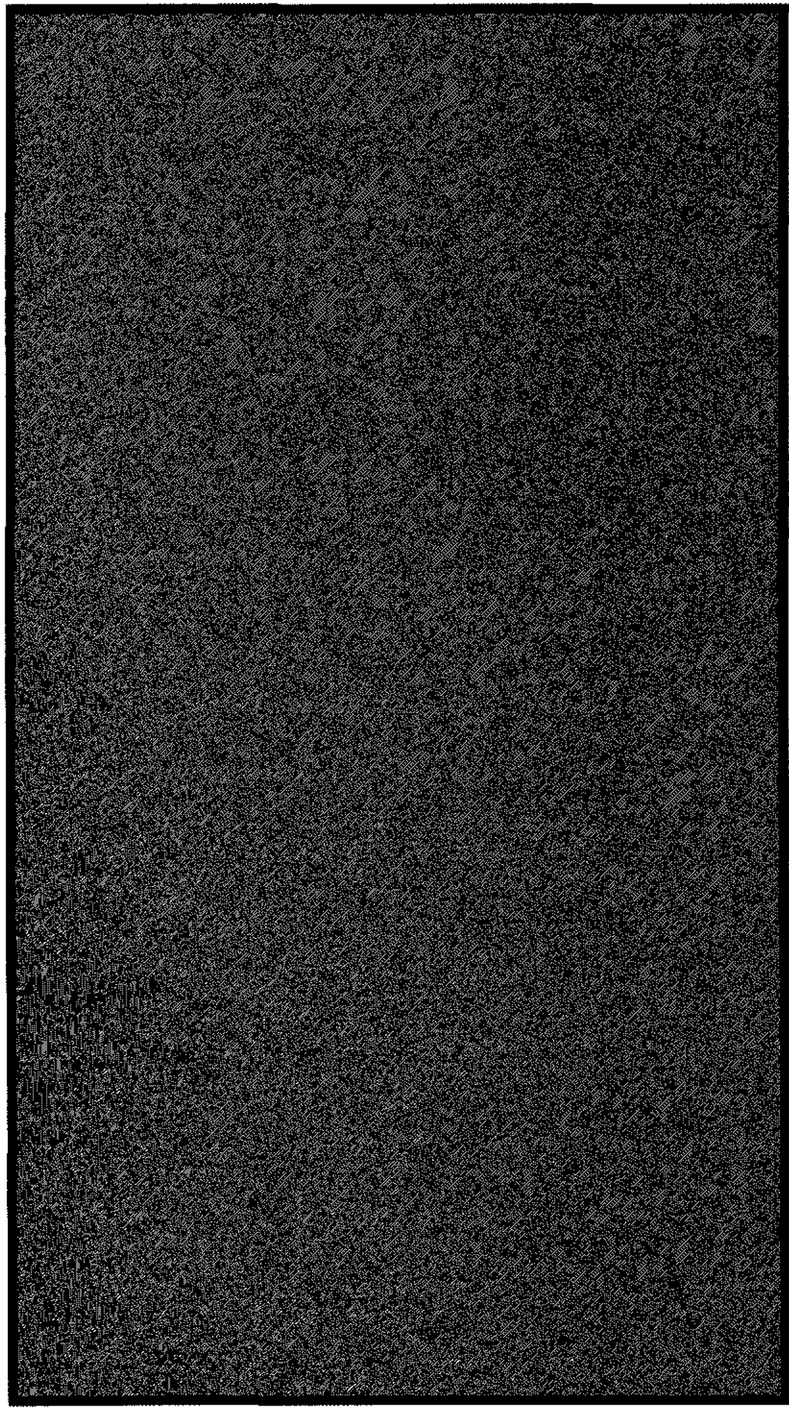
10.10

composite materials applications

Fibred fabric-reinforced laminated materials that are both strong and stiff do not have a clear advantage over metals with comparative properties. They are however vastly superior when compared with the strength-to-weight ratio. The composite material (modulus lamination per weight) and (strength per unit weight) is what gives a clear advantage over tradional non-laminated materials.
This factor is particularly recognisable in the transport industry where weight to power ratios mean higher energy efficiency with less product servicing.

The following table shows common applications for fibred fabric-reinforced laminations.

industry	- examples
aircraft	- wings - fuselages - helicopter blades and skids
automotive	- body parts - bumpers - engine components - chassis
water craft	- hulls - masts - decking
sporting	- fishing rods - golf clubs - skis - canoes
furniture	- outdoor furniture - ladders - tables



There are three main points to be included in a definition of an acceptable composite material lamination for use in structural applications:

a) It must consist of two or more materials with distinctly different properties.

b) It can be made by mixing the separate materials in such a way that the dispersion of one material in the other can be controlled to achieve optimal properties.

c) The final laminated material is both superior and unique in its quality, compared to that of the individual materials.

Properties of composite materials need to be aligned both parallel to and at a right angle to the direction of the fibre. One of its outstanding advantages is that it allows the possibilty of introducing stiffness and strength into a product. In practice, a limited number of composite lamination combinations is used and selection is determined by the fabrication process, material capability, desired final properties and product costing.

With the underlying behavioural qualities of composite fabric materials helping to dictate performance outcomes, functional attributes must utilise or overcome some of the current manufacturing and process characteristics. These include the design of products with optimum fibre content (strength); the changes in material properties owing to humid enviornments and temperature fluctuations (structural stability); the design of composites' energy absorbing capability (kinetic return); the development of composite material resistance to strain, corosion and stress (production technique); and improving cyclic wear resistance (individual composite property mix). A successful composite transtibial artificial limb must aim to control all of these variables.

10.11

composite materials properties

The following table shows Material Property Values at 20°C

materials	density	heat resistance	elongation to fracture	coefficient of thermal expansion	tensile strength
measure (units)	(Mg m^{-3})	(^{0}C)	(%)	($10^{6}\,^{0}C^{-1}$)	(MN m^{-2})
tempered steel	7.85	800	28	11	600
nickel based alloy (Ni)	8.18	1100	26	16	1200
high strength alloy (Al-Zn-Mg)	2.80	350	11	24	503
glass fibre polyester resin unidirectional	1.93	250	1.8	11	750
carbon fibre polyester resin unidirectional	1.62	260	0.8	30	1400
Kevlar fibre polyester resin unidirectional	1.45	560	2.5	59	2800+

table 62

The combination of Polyester resin with carbon and/or Kevlar fabrics was recommended by two separate glass lamination manufacturing companies in New Zealand. Wellington Artificial Limb Centre currently uses Orthocryl sealing resin. A *methylmethacrylate based*, colourless, transparent two-component resin.

10.12

composite lamination processes

fig 128

It is important to recognise the effect that manufacturing and other production processes have on the final quality of the laminated component.

The manufacturing technique for this artificial limb required two types of composite lamination processes due to the properties of the fabrics, alloy mesh materials, and design development objectives. The initial prototyping stage uses the ‘Hand Lay-up’ lamination method while the final product uses ‘Resin Injection’ and ‘Vacuum Pressure Bag’. The rationale for using the Hand Lay-up method is because at this stage, of prototyping, the final desired structure has no need for load-bearing capibilities. While strength is very important to the functioning of this product, the objectives are form-based applications; zip attachment; final product formed design; socket surface area, and ankle attachment block.

This process involves a postive mould and the layering of fabrics and mesh over the mould and impregnating it with resin. Painting and/or rolling the resin into the fabric ensures a reasonable bond. Layers can be built up quite simply with this method, until the required thickness is achieved. Resinated layers will cure without applied heat or pressure. This method is also quicker in process than using a vacuum bag and suits the modelling/prototyping stage.

The Vacuum Injection method removes all air from the resin, fabric and mesh laminations (fig 128). The final structure while very strong is relatively easily acheived. This process also involves a positive mould of the final form. A PVA bag is then stretched over the mould and tied off over a vacuum pump outlet. Fabrics and mesh are then applied over the mould covering

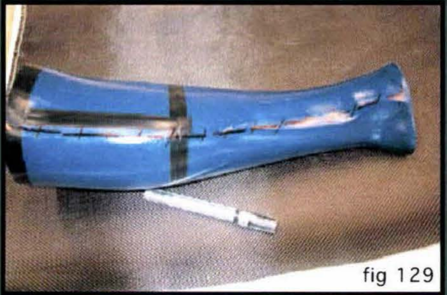


fig 129


fig 130


fig 131


fig 132

the prescribed surface area. A second vacuum bag is applied, covering the complete surface area and attached to the vacuum outlet. The injection of resin between the PVA bag composite layers will cause an even dispersement of resin over the surface area. The bags are then tied off and vacuum is applied. The end result is a load bearing exo-shell. This process is currently used in the prosthetic industry. It is important to acknowledge that if at any stage the pressure bag is punctured or pierced during the lamination process, the desired outcome will be jeopardised.

The initial prototyping during the design development stage required the construction of many form models to refine the design of the final product. As previously mentioned, using the hand lay method for this part of the study provided a quicker turn around time in product development. The following procedure describes the method used. A total of 18 prototypes and associated various parts were developed using this lamination techinque.

In (fig 129) shows a completed tibial mould ready for product form lamination. The outer covering on the tibial form requires a high gloss lacquer finish. The mould must be free of pits and cracks so the resin has little to cling to. The black tape on the mould is used to cover up the part seams so all that is left is a smooth total surface area. Note on the inside of the tibial mould (fig 129), a line is marked out vertically, running down the centre from top to bottom. The point of this line provides a guide for the direction of the fabric weave.

Carbon fabric cloth is then placed under the mould and wrapped twice around to determine the amount of cloth required for the lamination (figs 129/130). It is important to recognise that the lamination thickness will vary according to the amount of layering of cloth and the required structure strength. The structure in this case is only for form so two layers is realistically enough to represent the required thickness while also saving on materials and enabling material

fig 133

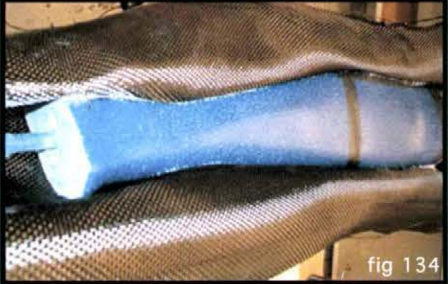


fig 134

fig 135

fig 136

manipulation for design criteria. This stage requires the mould to be mounted so it is free from any impending obstacles (fig 130). Any contact with either the cloth or resin while applying the lamination can lead to a very uneven surface covering and possible wastage of fabric. If this happens the laminated form is of little use. The application of a spray glue (figs 131/132), over the complete surface area of the mould provides two benefits to the hand lay process, the latter proving extremely sucessful. The initial reasoning for using the spray glue application was to provide a pliable sticky surface to the mould so the carbon fabric could be evenly attached to the required surface covering area (fig 133). Due to the unique curvature of the tibial form and the coarser fabric weave, the fabric must be evenly draped across the mould so the weave is running parallel to the guide line. The fabric weave line is running vertically down the outside of the tibial mould (fig 134). As the cloth is wrapped around the mould it conforms to the shape and in doing so contorts the weave (fig 134).

In (fig 135) the guide line runs along the top of the mould fabric line. It is at this point the fabric is most contorted. An allowance of a 3cm overlap before trimming ensures a cleanly moulded fabric edge. The cutting of the carbon fabric when unmoulded will cause instant fraying of the very fine carbon strands. The use of the spray glue to hold the fabric edge in place is very important. It should also be noted that any contact between a user's glove, spray glue and the cut edge of carbon fabric will cause destruction of the fabric.

The bottom part of the fabric is then pulled carefully up over the edge and trimmed (fig 135). The guide line is then taped (fig 135) allowing for an unresinated overlap after resin application. Any excess fabric is trimmed and disposed of. The polyester resin can be quickly applied (fig 136) and rolled over the surface area of the fabric. An even dispersement of resin over the surface area is essential for a clean structural finish. Once completed the tape is removed allowing two clean part lines to be cut down the length of the exo-shell.

10.13

exo-shell application

The initial product proved to be very successful in the form replication of the natural shape of the missing limb. This exo-shell structure little load-bearing capacity and not nearly as strong as if it was constructed using the vacuum bag technique. In (fig 139), the unique composition of the carbon fabric in both resinated and unresinated form. Notice the pitting in the plaster tibial mould (fig 137), due to the release agent not working properly. The three layered exo-shell pictured in (fig 138) shows the cut guide line. The left over fabric is then moulded and resinated over the foam form of the transtibial residual limb. A final example in (figs 140/141) shows a very clean exo-shell of a 96 percentile female. The final form weighs 720 grams. Please note this excludes ankle block, foam liner and zip attachment. The exo-outer shell (fig 139), now resinated with the zip in place has a portion of fabic left unresinated. This piece is the tibial socket shell, which when unformed in this state can be resinated to fit any tibial residual limb


137


fig 138


fig 139


fig 140


fig 141

within 25%+/- of the natural volume and form. The tibial moulds at this stage (figs 143/144) have the ability to be mass manufactured and used for landmine victims or other causes. A range of exo-shell sizes (fig 145) shows examples of both fabric types and natural form variations. Different size tibial exo-shells can be pre-moulded using an ergonomically measured range of tibial volumes. Ethnicity and/or obesity would be contributing factors to size variations.

In (fig 146) a carbon Kevlar combination fabric lamination is used and (figs 145/146) uses just kevlar. The benefit of using Kevlar is in its strength, but it is very hard to work with. Cutting Kevlar is difficult due to the incredibly fine strands and requires serrated shears, once resined it is still very hard to evenly cut Kevlar.


fig 142


fig 143


fig 144


fig 145


fig 146

10.14

lamination problem identification

These are some of the lamination problems encountered during the prototyping process.

At this stage of exo-shell prototyping there were a lot of hit and misses during lamination moulding. Working from the positive mould using the hand lay lamination method,the first problem, later proved to be difficult to solve. The slow disintegration of the mould when removing the dry laminated exo-shell. Although using a release agent recommended by the suppliers of the polyester resin, a reaction caused by the porous properties of the finished mould caused the laminated shell to stick to the mould. Upon initially prying the exo-shell off the mould (figs147/148), some of the mould would come apart with it (figs 148/149). This resulted in the positive mould needing refinishing every time a lamination was completed, a time comsuming process. Ironically the more the recommended release agent was applied the worse the end result (fig 150). The end result of a carbon/kevlar fabric lamination (fig 151) was disastrous. Issues such as the lamination layers' tearing when being removed from the mould also caused problems during this process. Although the basic concept of the shaped exo-shell proved successful, a lot of time was put into trying to solve the core lamination release problem.


47


148


149


fig 150


fig 151


152


fig 153

Methods such as applying different types of top coat paint to to the transtibial mould, applications of various types of metal and plastic polishes, and wrapping the mould in plastic film all proved unsuccessful.

After 10 variations of release agent combinations, and needing to address the transtibial moulds top coat each time (figs 155-158) the solution presented itself quite by chance. As explained in the composite lamination process secton. A spray glue product was initially used sparingly as a way of cleanly attaching the carbon fabric over the surface area of the mould. During the manufacturing of the eleventh prototype, a heavier layer of spray glue was applied to the mould, upon time for the exo-shell to be removed, it came off very cleanly and did not affect the mould at all.


fig 154


fig 155

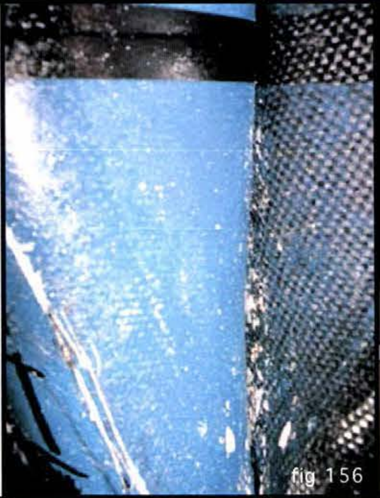


fig 156


fig 157


fig 158


fig 159

11.0

exotibius prototyping initial analysis and results

The objectives for this stage were to develop and analyse a transtibial shaped exo-skeletonal shell out of carbon fabric and polyester resin, using the positive moulding techinque (figs 160/161). The positive moulding hand lay technique provides an excellent prototyping foundation and structure to develop and refine the detailing design during the manufacturing process. While prototyping there were many smaller design details that required constant refinement, such as the application of the release agent over plaster moulds and trimming the resined form were all developed over time with trial and error. Early plaster mouldings delivered fantastic form studies using composite fabrics and the lamination process. The customised tibial shape is well emphasised using this process. The guide line is clearly defined in (figs 162-165). The electrical tape provides a barrier against the resin. Cutting a clean release line down the length of the shell is simpler when one edge is unresined fabric (fig 165).


fig 160


fig 161


fig 162

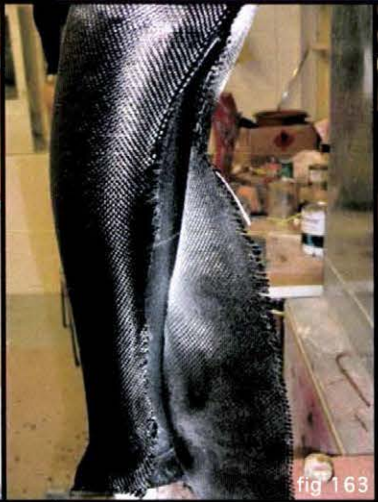


fig 163

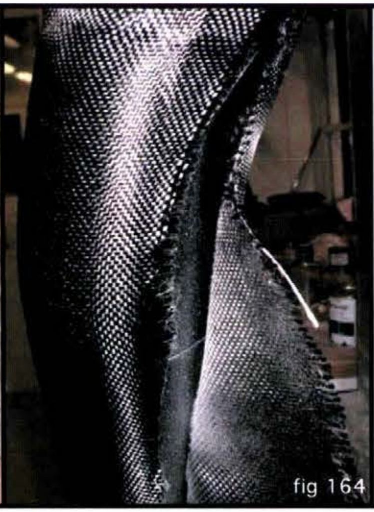


fig 164

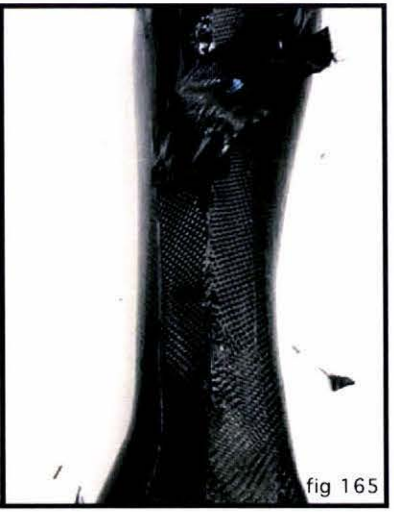


fig 165

The release of the resined shell from the plaster mould proved more difficult than originally thought. The supplied release agent had absolutely no effect. Early attemps to remove the shell too quickly resulted in the slow destruction of the plaster mould.

11.1

exotibius prototyping summary

The prototyping stage of the exo-shells was a steep learning curve in the application and process of laminating composite materials. In all there were in all 22 exotibius prototypes produced for this study before the design and the development process was finalised.

This is the recomendation for the prototype's final composite lamination layers (listed inside to out) are:

- Carbon Kevlar cloth
- Memory alloy mesh stocking (fine weave)
- Carbon fibre stocking
- Memory alloy mesh stocking (course weave)
- Carbon fibre stocking

The Cuban fibre outer layering was replaced with a clear Teflon lacquer based paint. The materials inability to cleanly cover the moulds total surface area during lamination application caused a deformed final mould.

Another mentioned problem encountered consistently during the initial prototyping stages was the slow destruction of the transtibial mould (figs 166-168) during exo-shell removal.


fig 166


fig 167


fig 168

The outer plaster mould fabrication was not ideally suited for this method of composite laminating. It would have been more beneficial to have covered the plaster mould with a thin outer layer of polished polyester resin. Due to the resin's hard finish when set, this would have provided the mould with greater protection. Constantly mending the mould after each lamination was very time consuming.

11.2

exotibius summary

The following issues were important factors in the prototyping of this transtibial artificial limb:

- The first and most important, was to cleanly define the natural form it was replicating. Once this was achieved by the sculptured mould, the design ideas could be introduced.
- Adding double exo-shell layers together (one inside the other,) allowed for the load bearing capabilities required. This product was designed to hold the weight of an amputee of up to 75kg.
- The vacuum bag resin injection laminating technique is the same method used as industry. It was important for production purposes to produce this prototype the same way.
- By using the vacuum bag method, the transtibial mould no longer required mending after a lamination was removed as it was protected by the vacuum bag.


fig 169


fig 170


fig 171


fig 172


fig 173


fig 174


fig 175

- The fins on the exo-shell can be cut out of the exo-shell using a CNC router.
- The separate pieces of the prototype need to be perfectly fitting.
- The ankle block must successfully hold a prosthetic foot.
- The zip in the socket must be accessible to the amputee.
- The unit is one complete piece, the only removable part being the breathable socket liner.

11.3

conclusion

This study introduced an 'Applied Human Aesthetic' design methodology to quantify a misrepresented product form and functional relationship. Salvador Dali's sculpture 'Homage to Newton' which symbolises the discovery of physical laws through open-mindedness, provided an icon for this study. The sculpture was also considered to provide an aesthetic imagery on which concepts for human prosthetics could be based. Background to the study was provided by a review of literature relating to applied human aesthetic, and analysis of aesthetic representation of form in nature. This led to definition of the human aesthetic experience as personal interpretation of material form. The results of a questionnaire showed that transtibial amputees had an interest in the design and development of their artificial limbs. Conclusions drawn from the results of the questionnaire are that amputees consider the operational function of their artificial limbs to be more important than their appearance and form. However, there were indications that greater emphasis should be given to the design attributes of artificial limbs which would reflect positively upon, and celebrate the user's condition.


fig 176

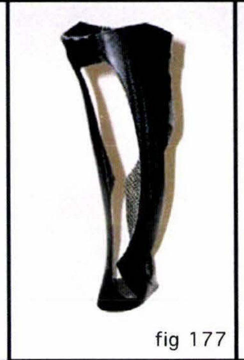


fig 177


fig 178

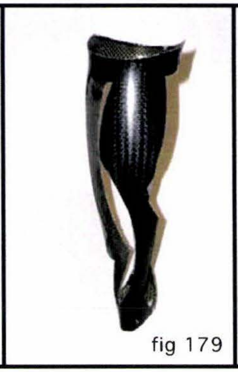


fig 179


fig 180

A prototype exotibius transtibial artificial limb was developed for this study. Its exoskeletal structure was shown to provide a kinetic return during motion, and a skin stocking can be rolled over the structure without affecting its performance. The exoskeletal design was also shown to be waterproof and capable of being used in a variety of environmental conditions. It can be manufactured and fitted at low cost using current industry techniques.

Comments sought from amputees in relation to the prototype exotibius transtibial artificial limb, show that it communicates a design aesthetic which is likely to enhance its product/human interaction qualities, and reflect positively on the user's condition.

11.4

evaluation

The central proposition of this project was to integrate an APPLIED HUMAN AESTHETIC methodology into the research, design and development of a transtibial artificial limb. Provoking an emotive reaction by the user's interaction with the prototype artificial limb, it was suggested their rehabilitation recovery time could be improved. While justification of this fact is outside the scope of this study, clinical trials would help qualify this suggestion, as well as develop and refine the product to a production stage.

This prototype has been designed and built to be used as a transtibial artificial limb. While this prototype is not fitted to any individual amputee due to ethical requirements, the next stage would be to do so. There are new areas of visual aesthetic and suggested functional design which are unique to this product (fig 181-185). It is necessary to trial these individual components, evaluate them, and conclude if their use is a viable alternative to what is currently available. Only then can this product achieve the research, design and development objectives.

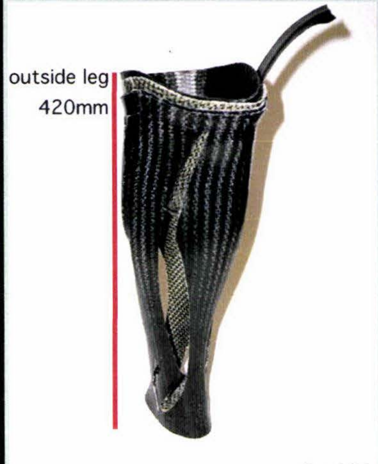


fig 181

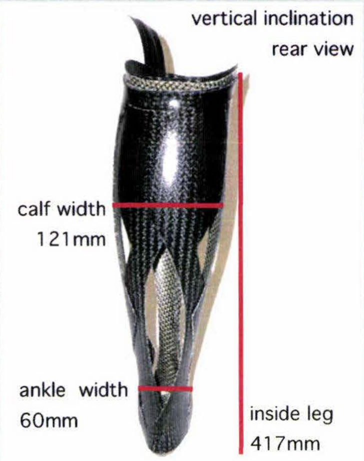


fig 182

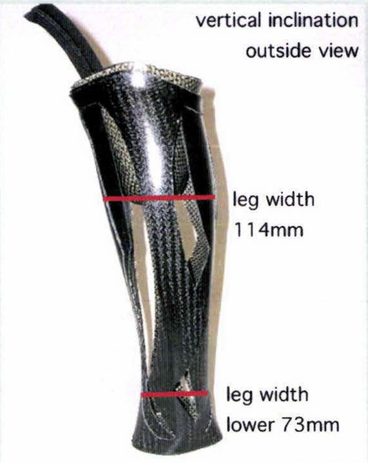


fig 183

fig 184

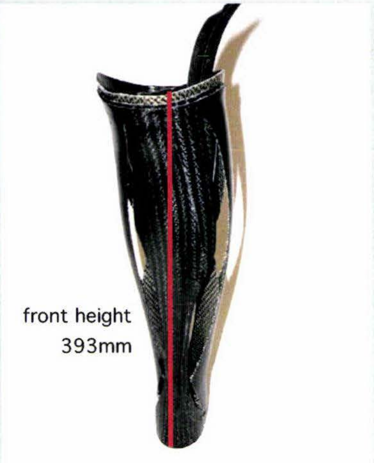


fig 185

fig 186

research presentation

The following chapter contains; questionnaire findings presentation, individual product feedback, and prototype evaluation and testing results.

An oral presentation of the questionnaire results was given at the New Zealand Artificial Limb ProsthOtics conference held in March 2006, Wellington, New Zealand. The 15 minute presentation in front of 200 people examined the questionnaire findings. The presentation findings caused a lot of excitement with conference participants, questions regarding further research in this area were common with a contingency from Belgium expressing a lot of interest in this subject. Their conclusions from the presentation included comments such as 'this is the only research of it's kind, we have seen nothing else like this yet, and we attend all over the world' J. Mueller (personal communication, March 25, 2006). The questionnaire presentation was also discussed positively at the following NZALB board meeting. Overall it is clear there is a lot of industry interest internationally, in this area of research, this warrants further examination. The researcher has since been accepted to present research findings at the 2006 JEGM Rehabilitation conference, The Netherlands.

The exotibius artificial limb was presented to randomly selected individuals attending the 2006 ProsthOtic conference. The aim was to receive anonymous critical product feedback. The overall response was extremely positive with most exclaiming they had never seen anything like it. Everyone was very excited by the visual form, and it was clear that participants were very interested in the exotibius artificial limb.

The limb's visual aesthetic aroused a lot of attention during individual show and tell seasons.

Comments such as 'it looks very futuristic,' 'I think it looks very interesting and would suit the younger generation of amputees' and 'I love the way it mimics the leg shape' clearly defined an excited response. A very interesting comment suggested that the exotibius 'looks very *masculine*'? 'I would enjoy wearing this at the beach, you would get a lot of looks just wearing it' and 'I like how you can roll coverings over it if you want to'. It is clear that the product's visual form created a lot of interest among participants. All seemed very interested in the visual approach taken by the designer, and expressed enthusiasm in this new direction of research and development.

Questions regarding the functional attributes were common with most participants asking 'has it been worn by anyone'? Participants were interested in it's attributes during active usage, participation in outdoor activities and sports being frequently mentioned. 'I could wear it in water and not worry about it filling up'. Generally all were very interested in it's possibility to function over a wider range of functional parameters than existing artificial limbs. Questions were also directed towards the interesting design and how it may function while walking, jogging and swimming both in sea and swimming pool.

As part of the evaluation and testing process it was necessary to establish the prototype's basic functional efficacy. The first stage of the evaluation involved product behaviour in various environments, the second stage involved static, dynamic and destructive load testing.

Prototype environmental testing involved three approaches; temperature fluctuation, UV degradation, and acidic/alkaline emersion. The first test set out to define how the prototype behaved in extreme temperature fluctuations. The prototype was initially heated in an oven at a constant 50 degrees Celsius for a period of 3 hours. Once removed the prototype did not display any form of visual degradation. The structural architecture maintained the designed shape and there was no noticeable weakness in the lamination when a load was applied. It is suggested that the prototype's kinetic return may be lessened at this temperature over long periods of time. The prototype was then frozen for a period of 24 hours. Upon inspection there was no visual degradation. The structural architecture maintained it's integrity and there was no noticeable de-lamination. The final part involved examining how the prototype reacted to extreme temperature variations, in this case approximately +/-53 degrees Celsius. Transference from freezer to oven and back to freezer over a period of 6 hours at 45 minute intervals produced an interesting result. The polyester lamination was affected where the ankle block meets the tibial fins. Hairline cracks were noticeable in the resin after static load was applied.

UV degradation was tested by leaving the prototype directly in direct sunlight over a period of 10 days. There was no visual degradation in the lamination after this period of time. There was however a very slight discolouration in the outer polyester resin. It is suggested that a clear lacquer sprayed over the prototype may counter this UV discolouration. The slight discolouration does not appear to affect the prototype's structural integrity.

The prototype was immersed in both fresh water and seawater over a period of 7 days each. Upon emerging from fresh water there was clear residue over the prototype. There was no structural damage when a static load was applied. Seawater also did not cause any structural damage when a static load was applied. There was however oxidisation residue over some surface areas of the prototype.


fig 187


fig 188

rototype load testing

Static and dynamic load testing involved applying downward forces to the prototype during the static and dynamic swing cycle. To achieve a successful replication of movement the prototype was anchor by the ankle block to a base plate and vertical loads were applied to a residual limb foam core and a carbon fibre residual bucket via a hydraulic press (table 63).

To measure applied loads, the prototype was measured down the central vertical axis at three different angles. These replicate three positions in phase two of the eight stage sub cycle. The first angle (fig 190) was measured at 183 degrees (+3.0 degrees to the downward load), the second (fig 191) at 203 degrees (-17 degrees to the downward load), the third (fig 189) at 163 degrees (+23 degrees to the downward load).

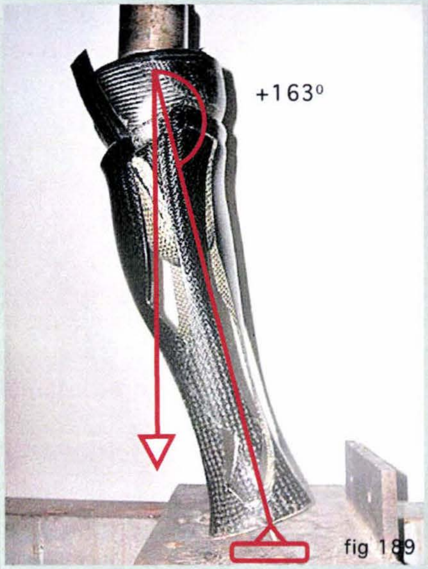


fig 189

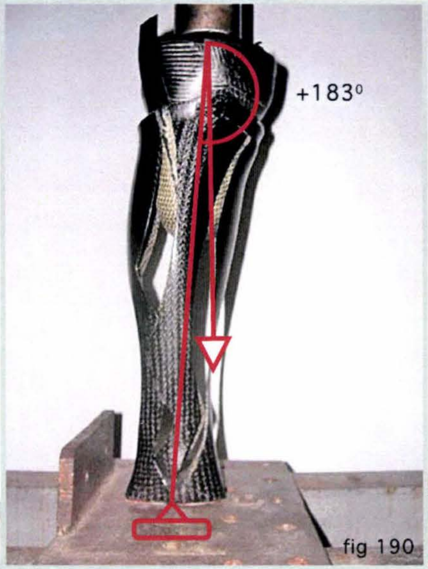


fig 190

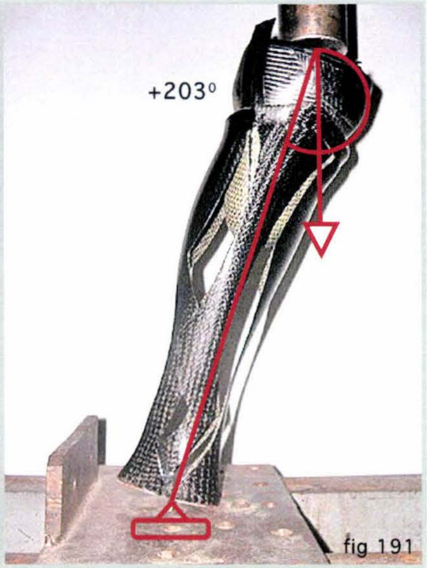


fig 191

The prototype was also measured across at the top along a horizontal axis (fig 192) for any twisting contortion. Table 63 outlines the results of the load testing.

A 50kg (base) load was applied at183 degree to the prototype, there was no flexion compression or twisting contortion observed. At 75kg the (static) load showed a little movement in flexion compression and no twisting contortion. At 100kg (dynamic) load, there was slight prototype flexion compression and no twisting contortion. The glue moulds around the ankle and residual socket appeared sound.

measure	base load	static load	dymanic load	destructive load
load angle to limb (degree)	+183	+183	+183	+183
applied load (kg)	50	75	100	178
vertical flexion compression (mm)	00	-3.0	-11	-31
horozontal twisting contorsion (degree)	00	00	00	-4.0
load angle to limb (degree)	+163	+163	+163	00
load (kg)	50	75	100	00
vertical flexion compression (mm)	00	-5.0	-12	00
horozontal twisting contorsion (degree)	00	00	00	00
load angle to limb (degree)	+203	+203	+203	00
load (kg)	50	75	100	00
vertical flexion compression (mm)	0	-5.0	-13	00
horozontal twisting contorsion (degree)	00	00	00	00

table 63

ergonomic evaluation

A prototype ergonomic evaluation was conducted to record; prototype destructive loading, product percentile range and interface impact.

A distractive load of 178kg at 183 degrees saw the prototype residual socket delaminate around the inside of the fin/socket wall, allowing the inside fin shell to separate. The point of failure of the prototypes socket wall is de-lamination (fig 196), this is dangerous as it could cause an amputee harm due to the explosive nature of de-lamination. Flexion compression was 31mm down the vertical axis and twisting contortion was -4 degrees (fig 192). Fig 193 shows the structural point of failure under twisting contortion. The forward fin requires strengthening to increase vertical loading and eliminate twisting contortion.

fig 192

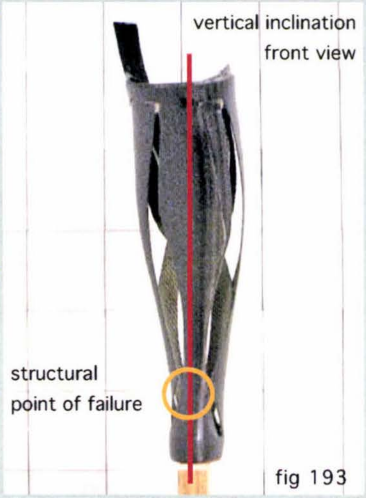


fig 193

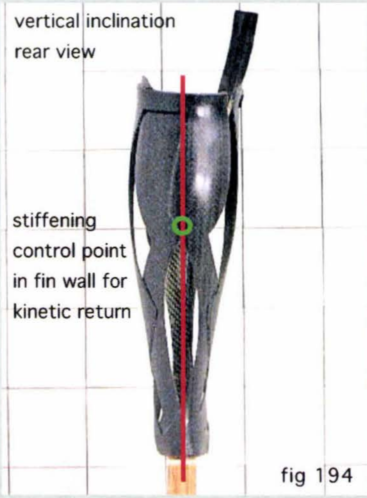


fig 194

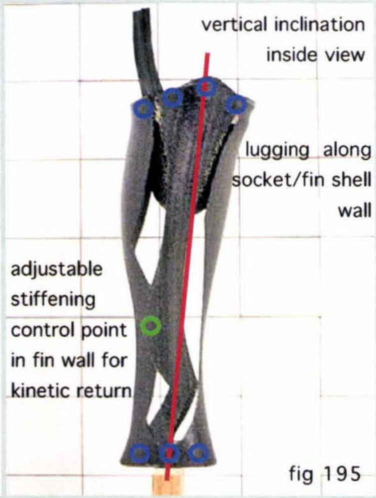


fig 195

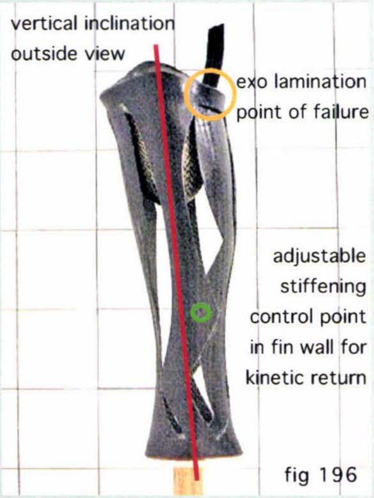


fig 196

There is a need to address the resin joins of the fin frame and the residual socket shell, as it is recommended that extreme dynamic loads on a 75kg female prosthetic limb should not exceed 200kg, 178kg is not strong enough. A secondary de-lamination fail safe system should be applied to the prototype. Lugging through the fin/socket wall and fin/ankle block (fig 195) would stop complete structural failure and lessen the chances of an amputee coming to harm.

The personalised customisation of the exotibius allows little disruption in product performance due to specific needs and/or aesthetic demands of the user. As discussed, this design involves replicating the natural missing form and volume in the structural architecture (figs 201, 202) while allowing kinetic return during movement. There are basic physical requirements an amputee must apply to such as mobility needs and weight. This prototype's fitted percentile range is dependent upon an amputee's personal fitting criteria as defined by a prosthesistist and the amputated residual limb rehabilitation stage. An ergonomic criterion is an amputee's weight at time of fitting, obese amputees (possibly due to diabetes mellitus) would not benefit from this prosthesis, as volume replication would hinder mobility and residual volume fluctuation hinder

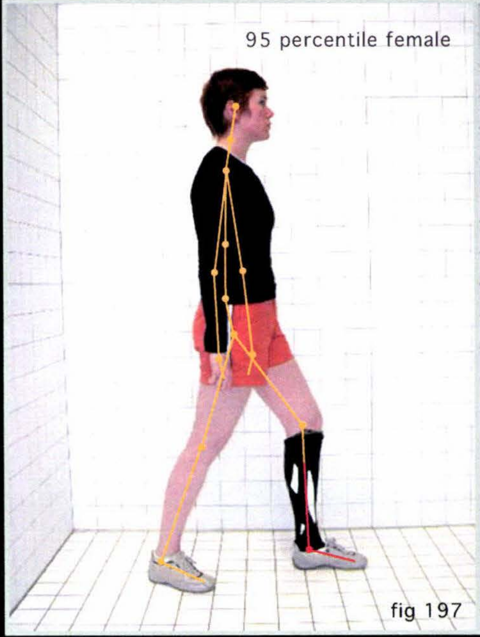


fig 197

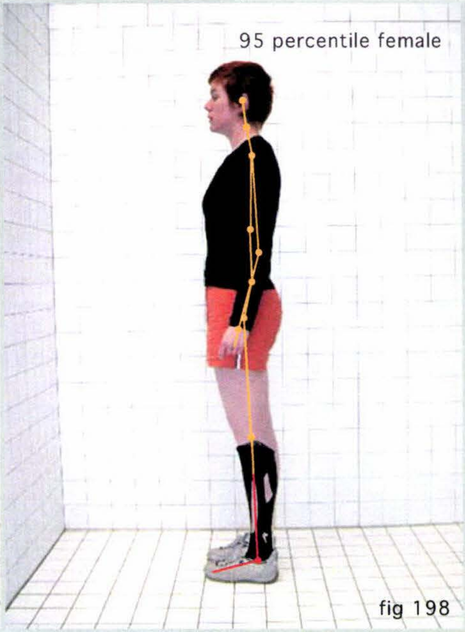


fig 198

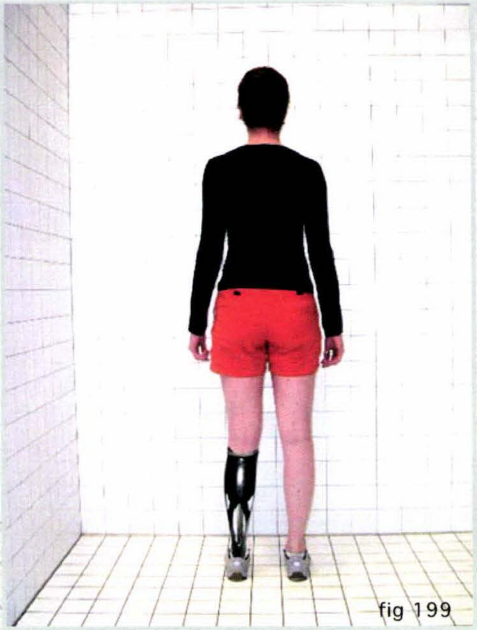


fig 199

fig 200

gait and prosthetic controls. The prototype was designed for a 97 percentile female amputee, measured form, volume and kinetic behaviour reflect this. This product is recommended for a male and female adult transfemoral and transtibial amputees, in the five to 97 percentile range. Figures (197-200) represent the prototypes visual impact and user interaction, it is clear that while the replicated volume has minimal interface impact, the prototypes carbon fibre finish does. This could be adjusted with a skin stocking if required by an amputee. The residual attachment (suspension) of the exotibius follows uses current industry methods, this design can also be utilised with any modular transfemoral knee joint (fig 203) while maintaining functional parameters. The exotibius aesthetic interaction should be pleasurable to the amputee and of visual interest to others. The design understands the need for positive interest and response, it is a conversation piece and should highlight disability.

fig 201

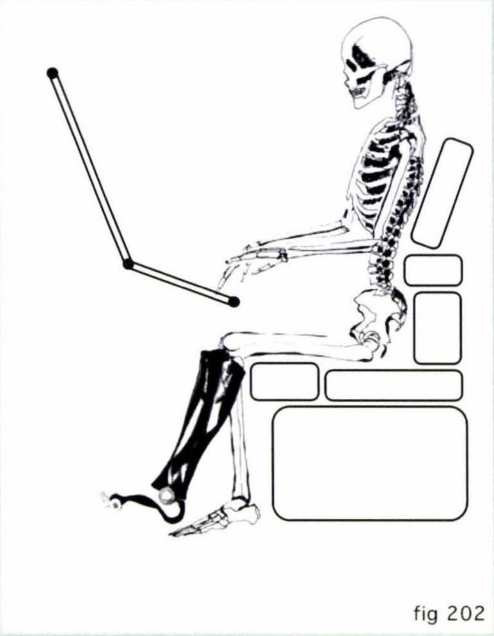


fig 202

fig 203

11.5

reflection


fig 204

This original exotibus design idea when shown at the ISPO Conference in Hong Kong was discribed by those who viewed it as 'unique and bold'. Peter Allen from the Wellington Artificial Limb Centre claimed that "the leg with the fins is a new idea, not seen before in our industry, it would be nice to take it further". At that point I was unaware of how much work lay ahead to achieve this goal.

There were many issues regarding concept design, development, and manufacturing processes still to be concluded. Working closely with Peter Allen at the Wellington Artificial Limb Centre helped me gain the knowledge required to successfully achieve the results. There was also a need to evaluate exactly what transtibial amputees thought of their artificial limbs. Gaining New Zealand Artificial Limb Board and New Zealand Health and Disability Ethics Committee permission to conduct a questionnaire was a major part of this process.

I have found it very rewarding to learn how much science has been applied to the prosthetic industry. The help, guidance and direction I have received from the people I have met during this study has been very much appreciated. The project could not have been achieved without their support.

12.0

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glossary

The following lists a glossary of terms.

Antropometrics:	human body measurements.
Applied human aesthetic:	artificial limb design methodology.
Architecture:	style + structure of building.
Bi-lateral amputee:	double amputation amputee.
Cuban fibre:	durable lightweight racing yacht sail cloth.
Endo-skeletal:	internal skeleton.
Exo-skeletal:	external skeleton.
Gait:	manner of walking or running.
Humanistic:	advancement of humanity by its own efforts, interest in welfare of people.
Interface:	point or boundary between two things.
Modular:	consisting of, or resembling a module or modulus.
Myoelectric:	robotic prosthesis using electronic sensors from nerve endings to drive functional controls.
Myographic:	graphical study of muscle structure and architecture.
Physiological:	the processes and functions of all or part of an organism.
Psychological:	relating to the mind or mental activity.
Residual limb:	remaining surface of amputated limb.
Rehabilitation:	physically or mentally disabled person's adaptation to society.
Sociology:	measurement of the development, organisation, functioning, and classification of human societies.
Sociometry:	study of sociological relationships within groups.
Suspension:	artificial limb attachment.
Transtibial:	across the tibia, i.e. below the knee.

Transfemoral:	across the femor, i.e. above the knee.
Trauma:	psychological and/or physical effects caused by powerful shock or injury.
Uni-lateral amputee:	single amputation amputee.

appendix a

New Zealand Health and Disability Ethics Application
2004 ISPO Hong Kong Conference abstract and Certificate
2005 Massey University College of Creative Arts
Conference Abstract and Presentation
2006 New Zealand ProsthOtics Conference abstract
2006 JEGM Rehabilitation Conference abstract
The Netherlands
Wellington City Council Creativity and Innovation Award
Massey University Celebration Research Award
Study correspondence

masters industrial design

applied human aesthetic in artificial limb design research design development study

development study

NEW ZEALAND ARTIFICIAL LIMB BOARD

HEAD OFFICE: 59 Adelaide Road, Newtown, P.O. Box 7281, Wellington, New Zealand.
Telephone: (04) 385 9410 Fax: (04) 385 9412

11 May 2005

TO WHOM IT MAY CONCERN

Massey University
Wellington

Approval of Questionnaire to Amputees

Daniel Buxton's Project

This is to confirm that the New Zealand Artificial Limb Board has approved the distribution of questionnaires to selected amputees in the Wellington area for the purposes of Daniel Buxton's project. NZALB staff will ensure that privacy legislation is complied with when they contact amputees.

M Lineham

Marion Lineham
Executive Manager, Corporate

HEALTH
MANATŪ HAUORA

133 Molesworth St
P.O. Box 5013
Wellington
New Zealand
Phone (04) 496 2000
Fax (04) 496 2340

Ref. No ____________

3 August 2005

Mr Daniel Buxton
[redacted] Way
[redacted]
Wellington

Dear Mr Buxton

I have considered your proposed questionnaire to persons who are patients of the Artificial Limb Centre which you have advised has received ethical approval from the Massey University Human Ethics Committee.

Although the guidelines for when institutional ethics committees should refer studies to a health and disability ethics committee include research involving patients/clients of any organisation providing health services, because your questionnaire is anonymous and focuses on what amputees perceive to be necessary aesthetic qualities of prosthetic limbs, further ethical approval from a health and disability ethics committee is not required.

I wish you all the best with your research.

Yours sincerely

Sally Cook
National Coordinator
Ethics Committees

Massey University

This is to certify that

Daniel Buxton

has participated in the course on

UNDERTAKING RESEARCH WITH HUMAN PARTICIPANTS

conducted by the

TRAINING & DEVELOPMENT UNIT
in collaboration with the
MASSEY UNIVERSITY ETHICS COMMITTEE

Granted this 21st day of April 2004

Vice Chancellor

Director
Training & Development Unit

Te Kunenga
ki Purehuroa

Te Kunenga ki Pürehuroa

SCREENING QUESTIONNAIRE
TO DETERMINE THE APPROVAL PROCEDURE

Part A and Part B of this questionnaire must both be completed

Part A

The statements below are being used to determine the risk of your project causing physical or psychological harm to participants and whether the nature of the harm is minimal and no more than is normally encountered in daily life. The degree of risk will then be used to determine the appropriate approval procedure.

Does your Project involve any of the following?
(All questions must be answered. Please circle either YES or NO for each question)

Risk of Harm

1.	Situations in which the researcher may be at risk of harm.	YES [✓ NO]
2	Use of questionnaire or interview, whether or not it is anonymous which might reasonably be expected to cause discomfort, embarrassment, or psychological or spiritual harm to the participants.	[✓ YES] NO
3.	Processes that are potentially disadvantageous to a person or group, such as the collection of information which may expose the person/group to discrimination.	YES [✓ NO]
4.	Collection of information of illegal behaviour(s) gained during the research which could place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships.	YES [✓ NO]
5.	Any form of physically invasive procedure on volunteer participants, such as the collection of blood, body fluid or tissue samples, exercise regimes or physical examination.	YES [✓ NO]
6.	The administration of any form of drug, medicine (other than in the course of standard medical procedure), placebo.	YES [✓ NO]
7.	Physical pain, beyond mild discomfort.	YES [✓ NO]
8.	The intentional recruitment of participants who are staff or students of Massey University. (Note: this question does not apply to evaluations as specified in No. 18 or anonymous questionnaires).	YES [✓ NO] Does not apply
9.	Any Massey University teaching which involves the participation of Massey University students for the demonstration of procedures or phenomena which have a potential for harm.	YES [✓ NO]

Informed and Voluntary Consent

10. The use of oral consent of participants rather than written consent.	YES [✓ NO]
11. Participants who are unable to give informed consent.	YES [✓ NO]
12. Research on your own students/pupils.	YES [✓ NO]
13. The participation of children (seven (7) years old or younger).	YES [✓ NO]
14. The participation of children under sixteen (16) years old where parental consent is not being sought.	YES [✓ NO]
15. Participants who are in a dependent situation, such as people with a disability, or residents of a hospital, nursing home or prison or patients highly dependent on medical care.	[✓ YES] NO
16. Participants who are vulnerable (e.g. the elderly, prisoners, persons who have suffered abuse, persons who are not competent in English, new immigrants).	YES [✓ NO]
17. The use of previously collected information or biological samples for which there was no explicit consent for this research.	YES NO

Privacy/Confidentiality Issue

18. Any evaluation of Massey University services or organisational practices where information of a personal nature may be collected and where participants may be identified.	YES [✓ NO]

Deception

19. Deception of the participants, including concealment and covert observations.	YES [✓ NO]

Conflict of Interest

20. Conflict of interest situation for the researcher (e.g. teacher/researcher, treatment provider/researcher, employer/researcher).	YES [✓ NO]

Compensation to Participants

21. Payments or other financial inducements (other than reasonable reimbursement of travel expenses or time) to participants.	YES [✓ NO]

Procedural

22. A requirement by an outside organisation (e.g. a funding organisation or a journal in which you wish to publish) for Massey University Human Ethics Committee approval.	YES [✓ NO]

Part B

The statements below are being used to determine if your project requires ethical approval of a Massey University Campus Human Ethics Committee and a Regional Health and Disability Ethics Committee.

Does your Project involve any of the following?
(All questions must be answered. Please circle either YES or NO for each question)

23. The use of District Health Board staff or facilities, or supported directly or indirectly in full or in part by District Health Board funds.	[✓ YES]	NO
24. Participants who are patients/clients of, or health information about an identifiable individual held by, an organisation providing health services (for example, general practice, physiotherapy, occupational therapy, sports medicine), disability services, or institutionalised care.	[✓ YES]	NO
25. Requirement for ethical approval to access health or disability information about an identifiable individual held by the Ministry of Health, or held by any public or private organisation whether or not that organisation is related to health.	YES	[✓ NO]
26. A clinical trial which: requires the approval of the Standing Committee on Therapeutic Trials; requires the approval of the Gene Technology Advisory Committee; is sponsored by and/or for the benefit of the manufacturer or supplier of a drug or device.	YES	[✓ NO]
27. Research in categories 23-26 involving New Zealand agencies, researchers or funds and undertaken outside New Zealand.	YES	[✓ NO]

Determine the type of approval procedure to be used:

If you answer YES to any of the questions 1 to 22 (Part A)	If you answer YES to any of the questions 23 to 27 (Part B)	If you answer NO to all of the questions *
•p	•p	•p
Prepare an application using the MUHEC Application Pack	[✓ Prepare an application using the MUHEC/Health & Disability Ethics Committee Application Pack]	Prepare a Low Risk Notification

•p

* Note - researchers who are new to the University, new to research with human participants or for whom Committee approval is desirable are welcome to send in a full MUHEC application, even if the Screening Questionnaire questions have all been answered "no".

Massey University
Te Kunenga ki Pūrehuroa

Application No: _____ / ___________
This number is assigned when your application is accepted. Quote on all documentation to participants and the Committee.

Human Ethics Committee

APPLICATION FOR APPROVAL OF RESEARCH TO BE SUBMITTED TO A HEALTH & DISABILITY ETHICS COMMITTEE

(All applications are to be typed and presented using language that is free from jargon and comprehensible to lay people)

1. **Project Title** APPLIED HUMAN AESTHETIC IN ARTIFICIAL LIMB DESIGN

Projected start date 16 JULY 2004 **Projected end date** 16 Sept 2005

2. **Applicant Details** *(Select the appropriate box and complete details)*

ACADEMIC STAFF APPLICATION

Full Name of Staff Applicant/s ....

School/Department/Institute ....

Region *(mark one only)* **Albany** ☐ **Palmerston North** ☐ **Wellington** ☐

Telephone .... **Email Address** ....

STUDENT APPLICATION

Full Name of Student Applicant DANIEL RICHARD SIMON BUXTON.

Employer (if applicable) ....

Telephone *644 4996209* **Email Address** D.Buxton@massey.ac.nz

Postal Address 16 Rangimarie Way, Wadestown, Wellington.

Full Name of Supervisor(s) Dr Duncan Joiner.
Senior Lecturer; Geoff Hargraves.

School/Department/Institute Dept of Industrial Design, Design, Fine Arts and Music.

Region *(mark one only)* **Albany** ☐ **Palmerston North** ☐ **Wellington** ☒

Telephone *8012794 X6868* **Email Address** D.A.Joiner@massey.ac.nz

3. **Type of Project** *(mark one only)*

Staff Research ☐

Student Research:
PhD Research ☐
Master's Research ☒
Honours Research ☐

Other ☐
If Other, specify: ____________________

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4. **Summary of Project**
Please outline in no more than 200 words in lay language why you have chosen this project, what you intend to do and the methods you will use.
(Note: all the information provided in the application is potentially available if a request is made under the Official Information Act. In the event that a request is made, the University, in the first instance, would endeavour to satisfy that request by providing this summary. Please ensure that the language used is comprehensible to all)

The key proposition of this design, develop study is to design development and prototype a Transtibial artificial limb prosthesis using the Transtibial muscled humanistic form as a product design, point of departure.

My research to date suggests that functional Transtibial artificial limb sections have more a machin visual quality rather than any human form. I suggest this may affect such issues as; cultural identi social and psychological factors, rehabilitation, recovery, self esteem and personal identity of an amputee. As part of this design development study I am interested in defining active Transtibial amputees, aesthetic visual preferences towards their prosthesis artificial limbs.

5. **List of Attachments** (tick boxes)

Completed Screening Questionnaire	X	Authority for Release of Tape Transcripts	
National Application Form	X	Advertisement	
Information Sheet/s *(indicate how many)*	5	Health Checklist	
Translated copies of Information Sheet/s		Questionnaire	X
Consent Form/s *(indicate how many)*	1	Interview Schedule	
Translated copies of Consent Form/s		Letter requesting access to an institution	X
Confidentiality Agreement *(for persons other than the researcher / participants who have access to project data)*	1	Letter requesting approval for use of database	1
Transcriber Confidentiality Agreement		Evidence of Consultation	X

Applications that are incomplete or lacking the appropriate signatures will be returned to the applicant for completion. This could mean delays for the project.

Please refer to the Human Ethics website (http://humanethics.massey.ac.nz) for details of where to submit your application and the number of copies required.

6. Declaration *(Complete appropriate box)*

ACADEMIC STAFF RESEARCH

Declaration for Academic Staff Applicant

I have read the Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants. I understand my obligations and the rights of the participants. I agree to undertake the research as set out in the Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants. My Head of Department/School/Institute knows that I am undertaking this research. The information contained in this application is to the very best of my knowledge accurate and not misleading

Staff Applicant's Signature .... Date: ....

STUDENT RESEARCH

Declaration for Student Applicant

I have read the Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants and discussed the ethical analysis with my Supervisor. I understand my obligations and the rights of the participants. I agree to undertake the research as set out in the Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants. The information contained in this application is to the very best of my knowledge accurate and not misleading

Student Applicant's Signature .... Date: ....

Declaration for Supervisor

I have assisted the student in the ethical analysis of this project. As supervisor of this research I will ensure that the research is carried out according to the Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants.

Supervisor's Signature .... Date: ....

Print Name ....

NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

Protocol number and date received (for office use only)

Part 1 : Basic Information

1. Full project title

APPLIED HUMAN AESTHETIC IN ARTIFICIAL LIMB DESIGN

2. Short project title (lay title)

Applied Human Aesthetic in Artificial Limb Design.

3. Principal Investigator's name and position

Daniel Buxton.

4. Address of Principal [redacted]

[redacted]	Work phone No.	[redacted]
[redacted]	Emergency No.*	[redacted]
Wellington	Fax	-
New Zealand	E-mail	D.Buxton@massey.ac.nz

5. Principal investigator's qualifications and experience in past 5 years (relevant to proposed research)

This Masters Design Development Study is a continuation from the Research and Development Study;

Buxton, D. (2003). 'The Artificial Limb.'
BDes, (Hon). Industrial Design.
Massey University School of Design, Fine Arts and Music.
Buckle Street, Wellington.
New Zealand.

Buxton, D. (2004). Artificial Limb Industrial Design. Applied Human Aesthetic in Artificial Limb Design. Innovations for Quality Living. Abstract Poster Presentation. ISPO.
The 11th World Congress of the International Society for the Prosthetics and Orthotics. Hong Kong Convention Centre.
Wanchai, Hong Kong.

- See Appended Document 1.

6. Co-investigators' name(s), qualifications and position(s) and, if more than one locality, Principal Investigator at **each** locality

A
B
C
D
E
F
G

7.1 Address of A above

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

7.2 Address of B above

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

7.3 Address of C above

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

7.4 Address of D above

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

7.5 Address of E above

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

7.6 Address of F above

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

7.7 Address of G above

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

(* option for Committee's information only)

8. Where this is supervised work

8.1 Supervisor's name: Dr Duncan Joiner.
Position: Professor of Design.
Day time phone number: 8012794 X6868

8.2 Signature of supervisor (where relevant)
Declaration: I take responsibility for all ethical aspects of the project

9. Is this a **Multi-Region** application ☐ Yes ☒ No
(includes a national study using a national database)

10. Is more than one Locality Organisation Involved ☐ Yes ☒ No

If 'yes", list the name and address of each Locality Organisation involved and complete the locality assessment approval in Part 4 (refer to Guidelines): N/A

11. I wish the protocol to be heard in a closed Meeting ☐ Yes ☒ No

If the answer is yes, provide reason why you wish it to be heard in a closed meeting: N/A

12. If the study is based, in part or in full, overseas, which countries are involved? N/A

13. Has ethics committee approval overseas been sought or obtained? (attach if available) N/A

14. Human Tissue – Does the project Involve collection or use of human tissue? ☐ Yes ☒ No
If **yes**, complete Part 5

15. Gene Studies – Does this research involve any gene or genetic studies? ☐ Yes ☒ No
If **yes**, complete Part 6

16. Consent - Are all participants able to consent themselves? ☒ Yes ☐ No
If **no**, complete section 7

17. Summary

Give a brief summary of the study (not more than 200 words, in lay language)

The key proposition of this design development study is to;
design, develop and prototype a tibial artificial limb prosthesis using the tibial muscled humanistic form as a product design, point of departure.
My research to date suggests that functional tibial artificial limb sections have more a machine like visual quality rather than any human form. I suggest this may affect such issues as; cultural identity, social and psychological factors, rehabilitation, recovery, self esteem and personal identity of an amputee.
As part of this design development study I am interested in defining active tibial amputees, aesthetic visual preferences towards their prosthesis artificial limbs.

18. Proposed starting date (dd/mm/yy): 16 July 2004.

19. Proposed finishing date (dd/mm/yy): 16 Sept 2005.

20. Duration of project (mm/yy): July 04 – Sept 05.

21. Proposed final report date (mm/yy): 16 Sept 2005.

Part 2 : Ethical Principles

A. VALIDITY OF RESEARCH *(Operational Standard Paragraphs 53-59)*

SCIENTIFIC BASIS

A1. Aims of Project

A1.1 What is the hypothesis/research question(s)? (state briefly)

A branch of industrial design is the application of 'humanistic factors' to product development and design.

- Current *'state of the art'* tibial artificial limb form, seems to provide an inconsistent humanistic communion with its coinciding functional attribute. [That of providing movement capabilities for transtibial amputees.]
- Physiological psychology suggests the functional attributes of tibial artificial limbs may enhance rehabilitation recovery processes.

Can we therefore suggest that if humanistic *form* or an *'Applied Human Aesthetic'* via the design process, is also included in the structural architecture, rehabilitation recovery processes may be improved exponentially?

A1.2 What are the specific aims of the project?

The aim of this design development study is to:

- identify active transtibial amputees, personal artificial limb/prosthesis aesthetic preferences;
- apply a formed human visual aesthetic to a tibial artificial limb/prosthesis without jeopardising any functional dynamics;
- application of a fabric carbon composites and memory alloy mesh, forming a humanistic
- exo-skeleton design structure replicating suggested localised kinetic muscle group action.
- production of a tibial exo-skeleton blueprint for manufacturing prototyping;
- design/develop of optional outer artificial skin layer.

A2. Scientific Background of the Research

Has this project been scientifically assessed by independent review? ☐ Yes ☒ No

If **yes**, by whom? (name and position)
A copy of the report should also be attached

If **no**, is it intended to have the project scientifically assessed, and by whom?

It is not intended for this project to be scientifically assessed. It will be open to review by New Zealand Artificial Limb staff if so requested.

Describe the scientific basis of the project (300 words maximum). Where this space is inadequate, continue on a separate sheet of paper. *Do not* delete page breaks or renumber pages.

- Recording of active transtibial amputees, personal artificial limb/prosthesis aesthetic preferences, via qualitative questionnaire.
- Investigation of application of fabric carbon composites and memory alloy mesh, forming a designed humanistic exo-skeleton structure replicating suggested localised muscle group kinetic action.
- Design development of humanistic exo-skeleton artificial limb form for transtibial amputees.
- Design development of artificial limb prosthesis molding technique.

A3. Study Design

A3.1 Describe the study design. Where this space is inadequate, continue on a separate sheet of paper. *Do not* delete page breaks or renumber pages.

The study design involves refining the communion between 'necessity product design' (those who require an applied product for everyday well being) and human/product interfacing, (that product in which functional attributes dominate product form and behaviour.)
A tibial artificial limb is such a product. This products visual form is completely dominated by the required functional attributes.
There seems to date, little effort by engineers to replicate the visual humanistic form. Currently the tibial artificial limb/prosthesis is at a stage where the product form is so visually foreign, (driven by these functional attributes) one may argue, the visual effect of this object attached to a transtibial amputee may hinder the self recovery/rehabilitation process.

A3.2 Is the method of analysis : ☐ quantitative ☒ or qualitative?

If the method of analysis is qualitative, go to question 3.3

If the method of analysis is **wholly or partly quantitative**, complete the following :

A3.2.1 Describe the statistical method that will be used

A3.2.2 Has specialist statistical advice been obtained? ☐ Yes ☐ No

If **yes**, from whom?

(A brief statistical report should be included if appropriate)

A3.3 If the method of analysis is **wholly or partly qualitative**, specify the method. Why is this method appropriate? If interviews are to be used include the general areas around which they will be based. Copies of any questionnaires that will be used should be appended.

- The method of data collection for this study is via an anomous questionnaire.
- The questionnaire is to be handed out by New Zealand Artificial Limb Wellington staff to what they consider to be an 'active transtibial trauma amputee'.
- All questionnaires will have enclosed a self addressed return envelope.
- At no stage during this process will the identity of the participated be disclosed.

A4. Participants

A4.1 How many participants is it intended to recruit? (Include details for each locality organisation)

- All participants will be recruited from New Zealand Artificial Limb Wellington.

The primary target group is:

- Physically active transtibial trauma amputees;
- 30 participants maximum; 10 participants minimum;
- Wellington branch, New Zealand Artificial Limb.

A4.2 If randomisation is used, explain how this will be done

All participants are to be picked by suitably qualified staff at Wellington, New Zealand Artificial Limb.

A5. Expected outcomes or impacts of research

A5.1 What is the potential significance of this project for improved health outcomes?

The possible applications for improved health outcomes are:

- artificial limb prosthetic personalised humanistic tibial sectioned limb form;
- carbon laminated exo-skeleton tibial artificial limb with weight reduction;
- zip up socket suspension attachment with residual total surface area pressure/temperature control;
- artificial skin for ethnic identification.

A5.2 What is the potential significance of this project for the advancement of knowledge?

- There is no recorded data to date that I have discovered, involving transtibial amputees artificial limb/prosthesis personal aesthetic preferences in New Zealand.
- All artificial limb design development to date in New Zealand is currently limited to para-athletic and extreme para-sporting activities.

This study therefore contains the first known New Zealand based design/development study into everyday tibial amputees artificial limb prosthesis aesthetic preferences.

It will also provide a platform for the further study of:

- carbon lamination exo-skeleton artificial limb design and development;
- amputee artificial limb ethnic identity options;
- socket suspension attachment variations;
- silicon based skin stocking.

A5.3 What steps will be taken to disseminate the research results?

All collected information will be reported in and available from:

- Buxton, D. (2005). MDes. Master Design Development study.
  'Applied Human Aesthetic in Artificial Limb Design'.
  Massey University School of Design, Fine Arts and Music. Wellington. New Zealand.

A6. Publication of Results

Will any restriction be placed on publication of results? ☐ Yes ☒ No

If yes, please supply details

A7. Budget

A7.1 How will the project be funded?

This project is personally funded.

A7.2 Does the researcher, the host department, the host institution or the locality organisation, have any financial interest in the outcome of this research? If "yes", please give details.

I have a personal financial interest in the outcome of the artificial limb/prosthesis design, development, patents and manufacturing rights.

A8. Incentive Payments - before completing this question, have you read the relevant section in the Guidelines for Completing the National Application Form? ☒ Yes ☐ No

A8.1. Will the researcher, the host department, the host institution, the locality organisation or any individual/organisation who recruits participants into studies but who will not be involved in the research as investigators receive payment (in money or kind) or reward in connection with this project – including any payment (in money or kind) or reward for recruiting participants into the project?

☐ Yes ☒ No

Note: Details about any payment (in money or kind) or reward made to **participants** recruited into the project are to be provided in Question E10.

A8.2 If "yes" to 8.1, please provide details.

Will the payment or reward be made directly to the researcher or to an audited research account or cost centre?

Will the payment or reward be for early or complete recruitment of a specified number of participants?	
What will be the amount of the payment or reward (indicate whether this will be per patient or lump sum)?	

B. Minimisation of Harm *(Operational Standard Paragraphs 60-68)*

B1. How many visits/admissions of participants will this project involve? Give also an estimate of total time involved for participants.

Each participant will be required to fill out and return a 12 page questionnaire.
The suggested time required for this task is between 15 and 45 minutes.

B2. Who will carry out the research procedures?

Daniel Buxton.

B3. What other research studies is the lead investigator currently involved with?

There are no other research studies I am currently involved in.

B4. Where will the research procedures take place?

- All gathered data will be summarised and stored at:
  [redacted]
  Wellington.

- All participating candidates will receive the questionnaire from staff at:
  New Zealand Artificial Limb, Wellington.
  Mein Street,
  Newtown,
  Wellington.

B5. Give a justification for the number of research participants proposed, using appropriate power calculations.

Justification for the number of research participants is based the availability of active transtibial trauma amputees located within the serviced NZ Artificial Limb Wellington, localised region.

B6. Are participants in clinical trials to be provided with a card confirming their participation, medication
and contact phone number of the principal investigator? ☐ Yes [X*] No

B7. Is it intended to inform the participant's GP of individual results of the investigations, and their

If **no**, outline the reasons

RE: B6. *All participants are supplied with a contact phone number and email address. This is for any questions that may arise during questionnaire participation.

B8. How do the research procedures differ from standard treatment procedures?

N/A

B9. What are the benefits to research participants of taking part?

- The short term benefits to amputee research participants of this study, will be of personal interest and inclusion in study only.
- It is suggested that the long term benefits of this study, be aimed towards satisfying the personal aesthetic requirements of amputees and their artificial limb/prosthesis.

B10. Briefly describe the inclusion/exclusion criteria and include the relevant page number(s) of the protocol or investigator's brochure.

Questionnaire package participant document contents consists of:
Page:
1. Cover Sheet;
2. Introduction;
3. Privacy Confidentiality Statement;
4. Questionnaire Objective;
5. Sampling Group;
6. Administration;
7-17. Questionnaire.

Return Envelope.

B11. Describe any methods for obtaining information. Attach questionnaires and interview guidelines (If NHI information is used, see Guidelines)

See attached Questionnaire package document.

B12. What are the physical or psychological risks, or side effects to participants or third parties? Describe what action will be taken to minimise any such risks or side effects.

There is considered no physical or psychological risks or side effects to questionnaire participants.

B13. What facilities/procedures and personnel are there for dealing with emergencies?

There is considered no emergency facilities/procedures required for questionnaire participants.

B14 What arrangements will be made for monitoring and detecting adverse outcomes?

All questionnaire monitoring/detecting of adverse outcomes will concluded within the context of this study, once questionnaires have been returned and raw data summarised.

B15. Is the trial being reviewed by a data safety monitoring board? ☐ Yes ☒ No

If yes, who is the funder of the DSMB? ☐ HRC ☐ Sponsor

B16. What are the criteria for terminating the study?

This Questionnaire is terminated if NZ Artificial Limb, Wellington cannot provide at least 10 active transtibial amputees to consent to the undertaking of the Questionnaire.

B17. Will any potential toxins, mutagens or teratogens be used? ☐ Yes ☒ No

If **yes**, specify and outline the justification for their use

B18. Will any radiation or radioactive substances be used? ☐ Yes ☒ No

Note: If any form of radiation is being used please answer the following. If no, go to question B19

B18.1 Under whose license is the radiation being used?

B18.2 Has the National Radiation Laboratory (NRL) risk assessment been completed? ☐ Yes ☐ No

If **yes**, please enclose a copy of the risk assessment, and the contact name and phone number

If **no**, please explain why

B19. Will any drugs be administered for the purposes of this study? ☐ Yes ☒ No

If **yes** is SCOTT approval required? ☐ Yes ☐ No

Has SCOTT approval been given? (please attach) ☐ Yes ☐ No

B20. Does the study involve the use of healthcare resources? ☐ Yes ☒ No

If **yes**, please specify:

This study requires the staff resources of New Zealand Artificial Limb, Wellington.

B21. What effect will this use of resources have on waiting list times for patients ie., for diagnostic tests or for standard treatments?

Staff will be required to past out packaged questionnaires only, to the primary target group.
This should not affect any existing patient services supplied by NZ Artificial Limb, Wellington.

C. Compensation for Harm Suffered by Participants *(Operational Std Paragraphs 83-91)*

(refer to Appendix 3 of the Guidelines)

Is this a clinical trial under accident compensation legislation (see form guidelines) ☐ Yes ☒ No

If **no**, go to question D. If **yes**, please answer the following:

C1. Is the trial being carried out principally for the benefit of a manufacturer or distributor of the drug or item in respect of which the trial is taking place? ☐ Yes ☐ No

(a) If the answer to 1 is **yes**, please complete **Statutory Declaration Form B** and answer questions C2, C3, C4 and C5.

(b) If the answer to 1 is **no** please complete **Statutory Declaration Form A and go to question D.**

C2. What type of injury/adverse consequence resulting from participation in the trial has the manufacturer or distributor undertaken to cover? (please tick the appropriate box/es)

		Yes	**No**
(a)	any injury (mental or physical)	☐	☐
(b)	only serious or disabling injuries.	☐	☐
(c)	only physical injuries	☐	☐
(d)	only physical injuries resulting from the trial drug or item, but not from any other aspect of the trial	☐	☐
(e)	physical and mental injury resulting from the trial drug or item, but not from any other aspect of the trial.	☐	☐

(f) any other qualification (explain)

C3. What type of compensation has manufacturer or distributor agreed to pay?

		Yes	**No**
(a)	medical expenses	☐	☐
(b)	pain and suffering	☐	☐
(c)	loss of earnings	☐	☐
(d)	loss of earning capacity	☐	☐
(e)	loss of potential earnings	☐	☐
(f)	any other financial loss or expenses	☐	☐
(g)	funeral costs	☐	☐
(h)	dependants' allowances	☐	☐

C4. Exclusion clauses:

		Yes	**No**
(a)	Has the manufacturer or distributor limited or excluded liability if the injury is attributable to the negligence of someone other than the manufacturer or distributor? (such as negligence by the investigator, research staff, the hospital or institution, or the participant).	☐	☐
(b)	Has the manufacturer or distributor limited or excluded liability if the injury resulted from a deviation from the study protocol by someone other than the manufacturer or distributor?	☐	☐
c)	Is company liability limited in any other way?	☐	☐

If yes, please specify

C5. Is the manufacturer/distributor's agreement to provide compensation in accordance with the RMI Guidelines attached? ☐ Yes ☐ No

D. Privacy and Confidentiality *(Operational Standard Paragraphs 44-49)*

D1. How will potential participants be identified?	As active transtibial (below knee) amputees.
D2 How will participants be recruited? (e.g. advertisements, notices)	By NZ Artificial Limb, Wellington staff.

D3	Where will potential participants be approached? (e.g. outpatient clinic) If appropriate, describe by type (eg students)	NZ Artificial Limb, Wellington. Mein Street, Newtown, Wellington
D4.	Who will make the initial approach to potential participants?	NZ Artificial Limb, Wellington staff.
D5.	How will data including audio and video tapes, be handled and stored to safeguard confidentiality (both during and after completion of the research project)?	• All participants are responsible for/return of Questionnaires from time of acceptance. • All Questionnaires are supplied with a postage paid, self addressed envelope. • All completed data will be stored in a locked cabinet at my personal residence; 16A Rangimarie Way. Wadestown, Wellington.
D6.	What will be done with the raw data when the study is finished?	All raw data from Questionnaire will be destroyed by 16 July, 2009.
D7.	How long will the data from the study be kept and who will be responsible for its safe keeping?	All Questionnaire data will be kept for the period of 5 years from the start of this study, 16 July, 2004. Daniel Buxton is responsible for the safe keeping of data.
D8.	Who will have access to the raw data and/or clinical records during, or after, the study?	Dr Duncan Joiner. Daniel Buxton.
D9.	Describe any arrangements to make results available to participants, including whether they will be offered their audio tapes or videos.	All participants will have the opportunity to study the results of Questionnaire once the study is completed and published.

E. Informed Consent

(Operational Standard Paragraphs 28-43)

Consent should be obtained in writing, unless there are good reasons to the contrary. If consent is not to be obtained in writing the justification should be given and the circumstances under which consent is obtained should be recorded. Attach a copy of the information sheet and consent form.

E1.	By whom, and how, will the project be explained to potential participants?	The Questionnaire package document contains a full explanation of the Study and Questionnaire directions. Any further participant questions can be forwarded to Daniel Buxton via supplied email or phone.
E2.	When and where will the explanation be given?	Within the Questionnaire package document.
E3.	Will a competent interpreter be available, if required?	NO
E4.	How much time will be allowed for the potential participant to decide about taking part?	Participants must decide upon reading of Introduction document (pg 1) included in Questionnaire package document if they wish to take part or not.
E5.	In what form (written, or oral) will consent be obtained? If oral consent only, state reasons.	Acceptance of Questionnaire implies consent.

E6. If recordings are made, will participants be offered the opportunity to edit the transcripts of the recordings? ☐ Yes ☒ No

E7. Will data or other information be stored for use in a different study for which ethics committee approval would be required? ☐ Yes ☒ No

If **yes**, explain how

E8. Is there any special relationship between the participants and the researchers? e.g. doctor/patient, student/teacher

NO

E9. Will there be any financial cost to the participant, e.g. travel and parking costs? If so, will such cost be reimbursed? (refer to Guidelines)

NO

E10. Will any payments be made to participants or will they gain materially in other ways from participating in this project? ☐ Yes ☒ No

If **yes**, please supply details

F. Cultural and Social Responsibility *(Operational Standard Paragraphs 53-59)*

F1. Will the study drug/treatment continue to be available to the participant after the study ends? ☐ Yes ☒ No

If **yes**, will there be a cost, and how will this be met?

What will happen to participants on a placebo arm?

Note: This needs to be included in the Information Sheet.

F2. Have you read the HRC booklet, Guidelines for Researchers on Health Research Involving Maori"? ☒ Yes ☐ No

F3. Does the proposed research project impact on Maori people in any way? ☐ Yes X* No

F3.1 Explain how the intended research process is consistent with the provisions of the Treaty of Waitangi.

*Due to the anonymous nature of this Questionnaire it is unknown if any Maori participates will be involved.

- All advised precautions have been taken on advisement to ensure that the research process is consistent with the provisions of the Treaty of Waitangi.

- See Appended Document 2.

- All advised precautions have been taken on advisement to ensure that ANY ethnic minority involved as a Questionnaire participant will be treated with all ethical considerations.

  - See Appended Document 3a & 3b for Research Study proposed Ethical guidelines.
  - See Questionnaire Document for Questionnaire Ethical guidelines.

F3.2 Identify the group(s) with whom consultation has taken place, and attach evidence of their support.

Massey University Training and Development Unit;
- Undertaking Research with Human Participants 1;
- Undertaking Research with Human Participants 2;
- Undertaking Research with Maori, Multi-Cultural and International Participants 3.

Massey University Ethics Committee.

- See Appended Document 2.
- See Appended Document 3a & 3b for Research Study proposed ethical guidelines.

F3.3 Describe the consultation process that has been undertaken **prior** to the project's development

- Code of Ethical Conduct for Research, Teaching and Evaluations involving Human Participants.
- Massey University Training and Development Unit.
- Massey University Ethics Committee.

F3.4 Describe any ongoing involvement the group(s) consulted have in the project

N/A

F3.5 Describe how information will be disseminated to participants and the group(s) consulted at the end of the project

All recorded information and summaries will be available for viewing in this study upon completion via Massey University School of Design, Fine Arts and Music.

F4. Are there any aspects of the research which might raise specific cultural issues that are not noted in Questions F3.1-F3.5 (eg for Pacific or Asian populations?

☐ Yes ☒ No

If **yes**, please explain

F4.1 What ethnic or cultural group(s) does your research involve?

N/A

F4.2 Describe what consultation has taken place with the group(s) prior to the project's development

N/A

F4.3 Identify the group(s) with whom consultation has taken place and attach evidence of their support

N/A

F4.4 Describe any ongoing involvement the group(s) consulted have in the project

N/A

F4.5 Describe how you intend to disseminate information to participants and the group(s) consulted at the end of the project

N/A

Part 3 : General

Describe and discuss any ethical issues arising from this project, other than those already dealt with in your answers?

For all Ethical outlines regarding this Study and Questionnaire please refer to;
Appended Document 3a & 3b and Questionnaire Document respectively.

Thank you for your assistance in helping us assess your project fully

Please now complete:

- the declarations (Part 4)
- a Registered Drug Form (if applicable)
- Form A or B relating to accident compensation

Attach :
Refer to page 3 of the Guidelines to ensure all relevant documents are attached

Part 4 : Declarations

Full Project Title : ______________________________

____

Short Project Title : ______________________________

1. Declaration by Principal Investigator

The information supplied in this application is, to the best of my knowledge and belief, accurate. I have considered the ethical issues involved in this research and believe that I have adequately addressed them in this application. I understand that if the protocol for this research changes in any way I must inform the Ethics Committee.

NAME OF PRINCIPAL INVESTIGATOR (PLEASE PRINT):

SIGNATURE OF PRINCIPAL INVESTIGATOR:

DATE:

2. Declaration by Head of Department in which the Principal Investigator is located or appropriate Dean or other Senior Manager

I have read the application and it is appropriate for this research to be conducted in this department I give my consent for the application to be forwarded to the Ethics Committee.

NAME AND DESIGNATION (PLEASE PRINT):

SIGNATURE: INSTITUTION:

DATE: DESIGNATION:

- ***Where the head of department is also one of the investigators, the head of department declaration must be signed by the appropriate Dean, or other senior manager.***
- ***If the application is for a student project, the supervisor should sign here.***

3. Locality Organisation Approval

Locality Organisation Approval is being sought / is attached from the following locations :

FORM A

DECLARATION OF ELIGIBILITY OF A CLINICAL TRIAL FOR CONSIDERATION OF COVERAGE UNDER ACCIDENT COMPENSATION LEGISLATION

Instructions: This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the primary Ethics Committee together with the documents seeking ethical approval for the proposed study.

If the study is a multi-centre proposal, this form should only be sent to the primary committee.

The information provided must be sufficiently detailed to enable the Ethics Committee to be satisfied that the proposed research is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out.

The provision of this information will enable the ethics committee to be satisfied that participants in the clinical trial will be considered for coverage under accident compensation legislation, for injury caused as a result of their participation in the research.

DETAILS OF PROPOSED RESEARCH STUDY

- Title of research project:
- Name of Research Director/Investigator:
- Is the Investigator a Registered Health Professional — Yes No *tick or circle as appropriate*
- Location/s of proposed study:
- State number of participants:
- Organisations providing support ($ or "in kind") for the direct and indirect costs of the research.

Please provide names of organisations and the type of support provided.

- Relationship of proposed research to the pharmaceutical industry or other company involved in health research. Please describe the involvement of industry in your proposed research, and provide details of support to be received from them.

STATUTORY DECLARATION:

I______________(name, of town/city)______________ solemnly and sincerely declare that as director of the proposed research, the proposed study is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out.

And I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Name (please print)	Signature	this day of

before me

Name (please print)	Signature

A Justice of the Peace, or
A Solicitor of the High Court
or other person authorised to take a statutory declaration.

Warning: Please note that it is an offence under part VI subsection 111 the Crimes Act 1961 to make a false statutory declaration.

Note: Applicants conducting a research study which is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form B.

FORM B

DECLARATION OF PROVISION OF COMPENSATION FOR INJURY FOR PARTICIPANTS IN A RESEARCH STUDY FOR A PHARMACEUTICAL COMPANY OR ANY OTHER COMPANY INVOLVED IN HEALTH RESEARCH

Instructions: This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the appropriate Ethics Committee together with the documents seeking ethical approval for the proposed study and appropriate assurance from the pharmaceutical company or any other company involved in health research.

The information provided must be sufficiently detailed to enable the Ethics Committee to be satisfied that:

- the proposed research is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out;
- participants in the proposed research project will receive an acceptable level of compensation from a Pharmaceutical Company or any other company involved in health research in the event of injury to participants resulting from their involvement in the proposed research study.

DETAILS OF PROPOSED RESEARCH STUDY

- Title of research project:
- Name of Research Director/Investigator:
- Location of proposed study:
- Number of participants:
- Organisations providing support ($ or "in kind") for the direct and indirect costs of the research.

Please provide names of organisations and the type of support provided.

- Relationship of proposed research to the pharmaceutical industry or other company involved in health research. Please describe the involvement of industry in your proposed research, and provide details of support to be received from them.
- Details of Compensation to be provided to participants in the event of injury. Documents signed by the sponsoring Pharmaceutical Company or other company involved in health research must be attached.

STATUTORY DECLARATION:

I______________________(name, of town/city)____________________ solemnly and sincerely declare that as director of the proposed research, the proposed study is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out, and that in the event of injury arising from their participation in the research, an appropriate level of compensation, in line with the *New Zealand Researched Medicines Industry Guidelines on Clinical Trials - Compensation for injury resulting from Participation in Industry Sponsored Clinical Trials,* will be provided by ______________________ (name of Pharmaceutical Company or another company involved in the research project) as detailed in the attached documents.

And I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Name (please print) Signature this day of

before me

Name (please print) Signature

A Justice of the Peace, or
A Solicitor of the High Court
or other person authorised to take a statutory declaration.

Warning: Please note that it is an offence under part VI subsection 111 of the Crimes Act 1961 to make a false statutory declaration.

Note: Applicants conducting a research study which is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out should complete Form A

Registered Drug Form *(refer question B19)*

INFORMATION REQUIRED FOR TRIALS INVOLVING ADMINISTRATION OF DRUGS CURRENTLY REGISTERED IN NEW ZEALAND.

Trade name of drug:

Chemical name of drug

Pharmacological class:

Brief details of any special features:

(E.g., long half life, receptor selectivity)

Recommended dose range:

Form of administration in the study:

Known or possible interactions with non-trial drugs the participants may be taking:

Side effects and adverse reactions:

05/28
Applied human aesthetic in artificial limb design

Daniel Buxton (HEC: PN Application 05/28)
Department: Dept of Industrial Design, Design, Fine Arts & Music
Supervisor(s): Dr Duncan Joiner

The Massey University Human Ethics Committee: Palmerston North considered the above application at their meeting held on Tuesday 12 April 2005.

The application was provisionally approved, subject to the fulfilment of the conditions below to the satisfaction of Dr John O'Neill (Chair).

Please note that the Committee is always willing to enter into dialogue with applicants over the points made. There may be information that has not been made available to the Committee, or aspects of the research may not have been fully understood.

〈 Note: All public documents should be proof read before distribution to eliminate grammatical and other errors, e.g. spelling of Information Sheet and often.

- Document has now been fully edited and proof read.

〈 Note: The Committee felt that the wording of some questions may be difficult for some participants, e.g. Q15 and Q19.

- Questions 15, 19 and others have now been rewritten using more friendly 'Lay' terms.

PART 2

A1.2

〈 Clarify that the purpose of the application is to gain approval for the questionnaire phase of the study only, i.e. bullet point one.

- The purpose of this application is to gain approval to conduct an anonymous questionnaire. The subject being, transtibial amputees' personal aesthetic preferences regarding their artificial limb(s). The location being Wellington Artificial Limb Centre, 46 Mein St, Newtown, Wellington.

A7.2

〈 The Committee considers that there is no financial interest/conflict of interest for the applicant in this particular study.

PART 4: Declarations

〈 Please provide evidence of approval from the Artificial Limb Association.

- Please refer to the attached document.

CONSENT FORM

〈 Refer comments on the questionnaire. Given that the questionnaire is anonymous, the Consent Form is not required.

- The Consent Form has been removed.

Confidentiality Agreement

〈 Clarify who the Confidentiality Agreement is for.

-The Confidentiality Agreement is for participating amputees only.

Information Sheet

〈 The intended audience of the Information Sheet is unclear. Please clarify whether it is intended for NZ Artificial Limb.

-Addressed to New Zealand Artificial Limb Board.

〈 Information Sheets are normally written as an invitation to participate and in continuous prose. Please reconsider the user-friendliness of your bullet point format and layout.

-Information Sheet is for NZALB board members only. Bullet points have been adjusted. All participant information is included in questionnaire document.

〈 Remove "(where relevant)" parentheses from sub-headings.

- Removed.

〈 Participant Involvement: Please justify the following bullet point, or exclude: "Participants who withdraw are responsible for the return of uncompleted questionnaire ..."

- Statement has been removed from document.

〈 Remove Compulsory Statement 2 "Compensation for Injury" as it is irrelevant for a survey questionnaire study.

- Statement has been removed from document.

〈 Ensure the Committee Approval Statement is included in the information given out with the questionnaire: "*This project has been reviewed and approved by the Massey University Human Ethics Committee, Palmerston North Application 05/28. If you have any concerns about the ethics of this research, please contact Dr John G O'Neill, Chair, Massey University Campus Human Ethics Committee: PN telephone 06 350 5799 x 8635, email humanethicspn@massey.ac.nz*".

- Statement has been included in questionnaire document.

〈 Supply a copy of the amended Information Sheet.

- See attached document.

Letters to NZ Artificial Limb

〈 Supply copies of agreement to distribute questionnaire packages when received.

- I have enclosed letter stating permission to conduct questionnaire from NZALB. This permission includes agreement to distribute questionnaire packages by NZAL Wellington Artificial Limb Centre staff.

〈 Add a statement to clarify that you are requesting the Association to distribute packages on your behalf.

- Statement has been included in Information Sheet addressed to NZ Artificial Limb Board.

〈 Supply a copy of the amended letter.

- See attached document.

Questionnaire

〈 Incorporate the Massey University departmental letterhead in the questionnaire.

- Logo included in questionnaire document.

〈 Add a statement to clarify how participants have been identified, i.e. by NZ Artificial Limb.

- Statement added to Terms and Conditions.

〈 Add Participants' Rights (refer to the Information Sheet format on MUHEC website).

- Participants Rights has been added to questionnaire document.

〈 Clarify how participants will receive the results of the questionnaire. Note: This is a participant right.

- Participants may receive results of questionnaire upon the conclusion of study via Wellington Artificial Limb Centre staff.

- Statement added to Terms and Conditions.

〈 Remove instruction to 'initial please' from page one of main questionnaire (anonymous questionnaire).

- Instruction removed.

〈 Ensure the Committee Approval Statement is included in the information given out with the questionnaire: *"This project has been reviewed and approved by the Massey University Human Ethics Committee, Palmerston North Application 05/28. If you have any concerns about the ethics of this research, please contact Dr John G O'Neill, Chair, Massey University Campus Human Ethics Committee: PN telephone 06 350 5799 x 8635, email humanethicspn@massey.ac.nz".*

- Statement has been included in Participants Rights.

Please supply to the Secretary, one (1) copy of this email with the reply inserted under each point, plus any amended documents, which should clearly identify changes, made, e.g. using track changes, italics or bold font.

Yours sincerely

Dr John O'Neill, Chair
Massey University Campus Human Ethics Committee: PN
****

Ethics Administrator

Office of the Assistant to the Vice-Chancellor (Ethics & Equity)

Old Main Building, Turitea PN221

Massey University Te Kunenga Ki Pūrehuroa

Private Bag 11 222, Palmerston North

New Zealand

Phone 06 350 [illegible]

Email: [illegible]@massey.ac.nz

Fax 06 350 5622

Project INFORMATION SHEET.

Att: New Zealand Artificial Limb Board.
Wellington. New Zealand.

Application to conduct anonymous Questionnaire at:
Wellington Artificial Limb Centre,
46 Mein St, Newtown, Wellington.

Project Title:

Applied Human Aesthetic in Artificial Limb Design.

RESEARCHER INTRODUCTION:

Researcher: Daniel Buxton

[redacted]

Address: [redacted]

Contact email: D.Buxton@massey.ac.nz

Contact Cell: [redacted]

[redacted]

Research Undertaking: Master Degree in Industrial Design. MDes.

Massey University College of Creative Arts, Wellington.

Supervisor: Dr Duncan Joiner. 8015799 ex6868.

Email: D.A.Joiner@massey.ac.nz

Co-supervisor: Geoff Hargreaves. 8015799 ex6992.

Employment: I am currently a full time Post-Graduate student.

Applied Human Aesthetic in Artificial Limb Design.

This project is a product based design/development project. This project involves the design, development and prototyping of a tibial sectioned artificial limb to a manufacturing level, using an 'Applied Human Aesthetic' design development methodology. This product's target market is a Transtibial unilateral and bilateral trauma amputee.

Participant Recruitment:

I wish to recruit 30 participants from Wellington Artificial Limb Centre, for an anonymous questionnaire on 'amputee tibial artificial limb personal aesthetic preferences.

Suggested participants are to be 'physically active trauma transtibial amputees'.

I would like all eligible participants to be selected by Wellington Artificial Limb staff.

NZ Artificial Limb, Wellington staff will approach suitable participants and forward a prepared questionnaire document and letter of introduction.

The following criteria outline selected participants:

-adult;
-male or female;
-physically active;
-uni/bi-lateral;
-trauma tibial amputees.

- All persons who are NOT catagorised in the above listed criteria are excluded from questionnaire.

Questionnaire Participants:

Participant numbers are dependent on availability of candidates within the NZ Artificial Limb, Wellington regional area.

Maximum 30 participants, Minimum 10 participants.

Please note:

-There is no compensation/reimbursement, expenses/payments offered for participation.
-There is no physical risk or discomfort to participants at any time as a result of participation.
-Participants will be questioned regarding their personal aesthetic artificial limb preferences.

Project Procedures:

All gathered data, is subject to statistical analysis and will be analyzed and published by Daniel Buxton in MDes thesis 'Applied Human Aesthetic in Artificial Limb Design'. (2005).

Results of gathered data will be published in MDes thesis 'Applied Human Aesthetic in Artificial Limb Design'. (2005). Industrial Design Dept, Massey University College of Creative Arts, Wellington, NZ.

All gathered data is to stored in a locked filing cabinet at the residence of Daniel Buxton and will be disposed of by Daniel Buxton, on or before July, 2010.

A summary of project findings will be made available all participates via NZ Artificial Limb Wellington. [Subject to copyright, patent pending] All selected questionnaire participants are anonymous at all times.

Participant involvement:

The following list represents details regarding participant procedures and time involved:

a) Participants who are considered eligible by NZ Artificial Limb, Wellington will be forwarded a questionnaire package and letter of introduction by NZALB Wellington staff.

b) Participants who undertake the questionnaire, give their permission by the completion and return of questionnaire.

c) Approached participants are not obliged to undertake questionnaire.

d) Participants are responsible for returning completed questionnaire via supplied self addressed envelope by due date.

e) Participants should allow up to 30 minutes to complete questionnaire.

f) Participants have up to 30 days from acceptance, to complete and return questionnaire.

g) Participants may withdraw from completing the questionnaire at any time during participation.

h) Participants who agree to undertake the questionnaire do so as volunteers.

i) All participants may contact me via NZ Artificial Limb, or directly, [if they so chose] regarding any questionnaire information.

Participant's Statement of Rights:

You are under no obligation to accept this invitation.

If you decide to participate, you have the right to:

- decline to answer any particular question;
- withdraw from the study;
- ask any questions about the study at any time during participation;
- provide information on the understanding that your name will not be used unless you give permission to the researcher;
- be given access to a summary of the project findings when it is concluded.

Completion and return of the questionnaire implies consent.

You have the right to decline to answer any particular question.

Project Contacts

Participants are invited to contact Daniel Buxton (if they so choose) or his supervisor Dr Duncan Joiner, if they have any questions about the project.

All contact details have been included in Questionnaire Package and on INFORMATION SHEET.

Compulsory Statements

1. Committee Approval Statement

This project has been reviewed and approved by the Massey University Human Ethics Committee, Palmerston North Application 05/28. If you have any concerns about the ethics of this research, please contact Dr John G O'Neil, Chair, Massey University Campus Human Ethics Committee: PN Telephone 06 350 5799 x 8635, email humanethicspn@massey.ac.nz

Massey University College of Creative Arts.
Master Industrial Design.
TRANSTIBIAL ARTIFICIAL LIMB INDUSTRIAL DESIGN.
Applied Human Aesthetic in Artificial Limb Design
Research Design Development Proposal.

Daniel Buxton. [redacted]

Ethical Standards.

The following describes and lists the ethical conduct and concerns regarding this research design development study.

During the course of this design development study, ethical issues will arise regarding the use of test subject(s) and their interaction. In the interests of all who participate in this design development study, an unquestionable standard of ethical conduct shall be maintained at all times.

To manage this the following list of major ethical principles will be adhered to, (as outlined in Massey University, Code of ethical Conduct for Research, Teaching and Evaluations involving Human Participants)

Ethical principles to be considered are:
a) Respect for persons.
b) Minimisation of harm to participants, researchers, institutions and groups.
c) Informed and voluntary consent.
d) Respect for privacy and confidentiality.
e) The avoidance of unnecessary deception.
g) Social and cultural sensitivity to the age, gender, culture, religion, social class of the participants.
h) Justice.

- At no time during this design and development study will issues regarding Maori, their Iwi and The Treaty of Waitangi be effected. This will also apply to any ethnic minority/majority residing within New Zealand.
- At no stage during this design development study is there expected to be any unnecessary risk or harm to participants, researchers, institutions and groups.
- All participants will be adequately and appropriately informed about this study, their involvement and participation, consents and privacy.
- A written consent and privacy statement shell be provided and will be signed by consenting parties before any further action is undertaking.
- At no time shall any participating individual be identified unless previously agreed between respective parties.
- A confidentiality agreement must be acknowledge by both parties before any participation can take place.
- The confidentiality of all information obtained during this design development study will be respected except where disclosure is necessary to avoid *harm*.
- All attempts will be made to avoid any unnecessary deception during the design development study.
- The use of students in the initial early stage of the project will at no time interfere with their school work, line of study or attendance. Avoidance of conflict of interest will be taken very seriously at all times.
- At no time will children/minors (under the age of 18) be used at any time during this study.
- It is viewed that no form of community based research will be required for this study.
- Adequacy of Research. The researcher/designer will at all times undertake to achieve the outlined goals of this design development study. The researcher/designer being qualified in the appropriate field will at all times respond accordingly to the Supervisor's guidance.

5 July 2005.
Daniel Buxton.
1[redacted]
[redacted]
[redacted]
D.Buxton@massey.ac.nz

Att: Ms Marion Lineham.
cc: Mr Ray Binet. Mr George Mitchell.
Executive Manager, Corporate.
New Zealand Artificial Limb Board.
59-63 Adelaide Rd, Newtown.
Wellington, New Zealand.

Dear Ms Lineham,

My name is Daniel Buxton. I am currently undertaking a post graduate Master study in Industrial Design at Massey University College of Creative Arts, Wellington. This study is titled Applied Human Aesthetic in Artificial Limb Design.

The aim of this project is to design, develop and prototype a transtibial artificial limb prosthesis using the muscled tibial form as a product design point of departure.

I am writing to ask your permission to conduct an anonymous questionnaire over the duration of 4 weeks, of up to 30 'physically active' trauma transtibial amputees who are patients of Wellington Artificial Limb, New Zealand.

The questionnaires objective is to define, evaluate and assess transtibial amputees aesthetic visual preferences regarding their transtibial prosthetic artificial limb(s).

I would ask that all participants, be identified and approached with a supplied questionnaire package and result sheet by staff from Wellington Artificial Limb Centre, New Zealand.

The primary participant I require feedback from are 'physically active trauma transtibial amputees'. This questionnaire requires an anonymous response from all participants. At no time will their identity be revealed.

I have included with this letter a sample Questionnaire Package and Information Sheet. Should you have any questions please feel free to contact me at any time.

I do hope you are able to assist me. I look forward to your reply.

Kind Regards,

Daniel Buxton.

20 July 2005.
Daniel Buxton.
16A Rangimarie Way,
Wadestown, Wellington.
0212982684
D.Buxton@massey.ac.nz

Att: Mr George Mitchell.
New Zealand Artificial Limb Board.
59-63 Adelaide Rd, Newtown.
Wellington, New Zealand.

Dear Sir,

My name is Daniel Buxton. I am currently undertaking a post graduate Master study in Industrial Design at Massey University College of Creative Arts, Wellington. This study is titled Applied Human Aesthetic in Artificial Limb Design.

The aim of this project is to design, develop and prototype a transtibial artificial limb prosthesis using the muscled tibial form as a product design point of departure.

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The questionnaires objective is to define, evaluate and assess transtibial amputees aesthetic visual preferences regarding their transtibial prosthetic artificial limb(s).

I would ask that all identified participants, be identified and approached with a supplied questionnaire package and result sheet by staff from Wellington Artificial Limb Centre, New Zealand.

The primary participant I require feedback from are 'physically active trauma transtibial amputees'. This questionnaire requires an anonymous response from all participants. At no time will their identity be revealed.

I have included with this letter a sample Questionnaire Package and Information Sheet. Should you have any questions please feel free to contact me at any time.

I do hope you are able to assist me. I look forward to your reply.

Kind Regards,

Daniel Buxton.

20 July 2005.
Daniel Buxton.
[redacted]
D.Buxton@massey.ac.nz

Att: Mr Ray Binet
Wellington Artificial Limb Centre.
46 Mein St Newtown,
Wellington, New Zealand.

Dear Mr Sir,

My name is Daniel Buxton. I am currently undertaking a post graduate Master study in Industrial Design at Massey University College of Creative Arts, Wellington. This study is titled Applied Human Aesthetic in Artificial Limb Design.

The aim of this project is to design, develop and prototype transtibial artificial limb prosthesis using the muscled tibial form as a product design point of departure.

I am writing to ask your permission to conduct an anonymous questionnaire over the duration of 4 weeks, of up to 30 'physically active' trauma transtibial amputees who are patients of Wellington Artificial Limb, New Zealand.

The questionnaires objective is to define, evaluate and assess transtibial amputees aesthetic visual preferences regarding their transtibial prosthetic artificial limb(s).

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The primary participant I require feedback from are 'physically active trauma transtibial amputees'. This questionnaire requires an anonymous response from all participants. At no time will their identity be revealed.

I have included with this letter a sample Questionnaire Package and Information Sheet. Should you have any questions please feel free to contact me at any time.

I do hope you are able to assist me. I look forward to your reply.

Kind Regards,

Daniel Buxton.

administration/sampling group

Administration of the Questionnaire is as follows :

a) 30 numbered Questionnaire Packages will be forwarded to New Zealand Artificial Limb, Wellington.

b) Participants are to be identified as 'active transtibial amputees' by New Zealand Artificial Limb staff.

c) All participants will be selected and approached by a staff member from New Zealand Artificial Limb, Wellington.

d) Participants will receive a Questionnaire Package with letter of introduction.

e) Participants must read all information provided before undertaking answering the questionnaire.

f) PARTICIPANT COMPLETION AND RETURN OF QUESTIONNAIRE IMPLIES CONSENT.

g) a self-addressed, postage paid, RETURN envelope is provided.

h) Participants are asked to return Questionnaire answers within 20 days of receiving the Questionnaire package.

This design development study Questionnaire requires all participants to be physically active transtibial amputees. This Questionnaire requires the amputee to evaluate the visual aesthetic and basic functional performance of their prosthesis/artificial limb(s) .

The primary participant criteria are persons who are:

- trauma amputees;
- uni-lateral or bi-lateral transtibial amputees;
- adult;
- male or female;
- physically active on a weekly basis. (Participants are able to travel at least 1km per week under their own devices or without assistance. e.g. wheelchair.) An equivalent distance is 2-3 laps around the Basin Reserve.

applied human aesthetic in artificial limb design

master industrial design

development study

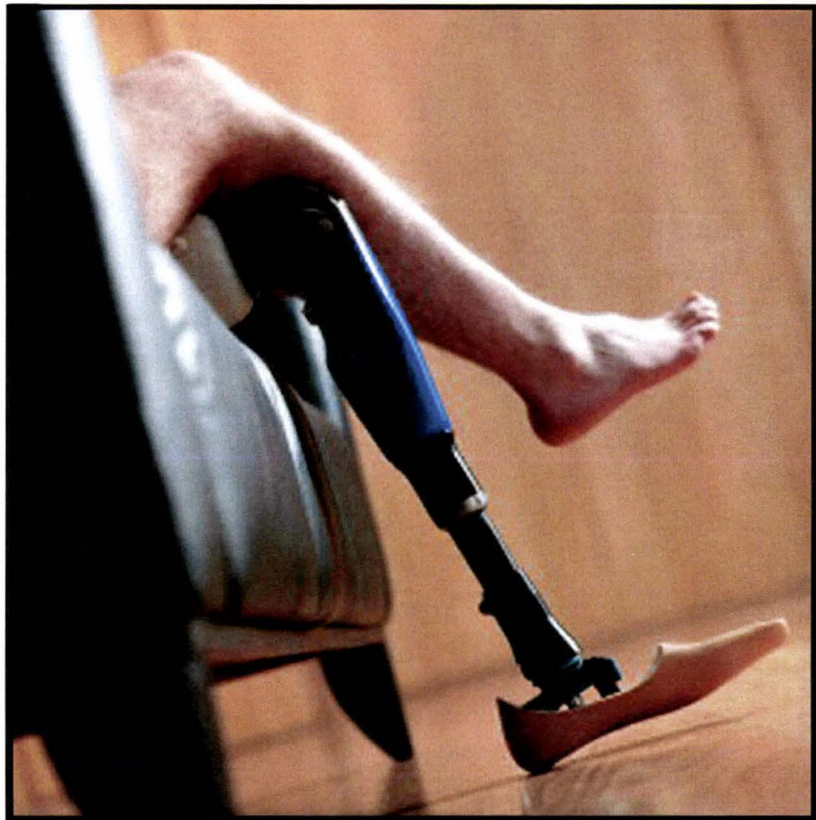
massey university college of creative arts, wellington

researcher : Daniel Buxton. BDes(Hons)

supervisor : Dr Duncan Joiner

co-supervisor : Geoff Hargreaves.

Massey University



“form follows function - that has been misunderstood.”

“ form and function should be one, joined in a spiritual ”

Frank Lloyd Wright.

introduction

To whom it may concern.

My name is Daniel Buxton. I am currently undertaking a post graduate study in Industrial Design at Massey University College of Creative Arts, Wellington. This study is titled Applied Human Aesthetic in Artificial Limb Design.

The aim of this questionnaire is to find out what you think about the visual appearance of your artificial limb.

Do you like the way it looks?

Do other people like the way it looks?

My research to date suggests that transtibial artificial limbs provide the user with the functions they require for mobility, but what about the visual quality?

What about:

- your cultural identity;
- social interaction;
- rehabilitation recovery time;
- self esteem;
- personal identity.

What do you think about these issues?

I would like to know.

objective

The objective of this questionnaire is:

a) -to find out how users of transtibial artificial limbs feel about their appearance of their limbs;

b) - to ask them how the appearance of their artificial limb could be improved.

participants' rights

Statement of Rights:

You are under no obligation to accept this invitation.

If you decide to participate, you have the right to:

- decline to answer any particular question;
- withdraw from the study;
- ask any questions about the study at any time during your participation;
- provide information on the understanding that your name will not be used unless you give permission to the researcher;
- be given access to a summary of the project findings when it is concluded.

COMPLETION AND RETURN OF THE QUESTIONNAIRE IMPLIES CONSENT.

This project has been reviewed and approved by the Massey University Human Ethics Committee, Palmerston North Application 05/28. If you have any concerns about the ethics of this research, please contact Dr John G O'Neil, Chair, Massey University Campus Human Ethics Committee: PN telephone 06 350 5799 x 8635, email: humanethicspn@massey.ac.nz

If you agree to participate in this anonymous questionnaire please read all attached documents.
At no time are these questions designed to cause offence.
When you are completed please return questionnaire in the self addressed envelope provided.
If you have any difficulties or questions regarding this questionnaire or my study, I can be contacted directly at:
email: D.Buxton@massey.ac.nz mobile: 0212982684
Supervisor: Dr Duncan Joiner. Professor of Design, College of Creative Arts, Wellington.
email: D.A.Joiner@massey.ac.nz

applied human aesthetic
in artificial limb design

confidentiality statement

TO ALL PARTICIPANTS.

Please read this privacy and confidentiality statement carefully.

This questionnaire titled 'Applied Human Aesthetic in Artificial Limb Design' is a Masters Industrial Design study by Daniel Buxton, at the Department of Industrial Design, College of Creative Arts, Wellington, New Zealand.

Terms and Conditions:

- Please return questionnaire in supplied envolope, by Augest 25th 2005.
- All suitable participants have been identified and chosen by staff from Wellington Artificial Limb Centre, New Zealand.
- All information gathered in this questionnaire is considered strictly private and confidential and the property of Daniel Buxton and Massey University College of Creative Arts.
- Participants may receive results of questionnaire upon the conclusion of study via Wellington Artificial Limb Centre staff.
- All design ideas, concepts and data gathered from the questionnaire are to be considered private and confidential at all times and will not to be discussed with third parties.
- At NO time will any data gathered from questions be shared with any other parties other than those listed above.
-This questionnaire will remain anonymous. At no time will your identity be revealed in this study.
- All information gathered in this questionnaire will be published by Daniel Buxton in the Masters study titled 'Applied Human Aesthetic in Artificial Limb Design' at Massey University Department of Industrial Design, College of Creative Arts, 2004/05.

questionnaire
applied human aesthetic
in artificial limb design

Massey University

transtibial amputee questionnaire

applied human aesthetic in artificial limb design

questionnaire

Please answer the following questions by placing a tick in the circle next to your answer.

1) How long have you been an amputee?

○ a) Under 1 year
○ b) 1-9 years
○ c) 10-19 years
○ d) 20-39 years
○ e) 40+ years

2) Which statement appropriately identifies you?

○ a) Uni-lateral transtibial amputee (*single below knee amputee*)
○ b) Bi-lateral *transtibial amputee* (double below knee amputee)
○ c) Lower *extremity amputee* (one above knee, one below knee amputee)

3) Is your artificial limb mainly used for stability and movement or as a visual aid to replicate the missing limb?

○ a) Stability and movement
○ b) Visual aid
○ c) Both stability, movement and as a visual aid

4) Currently, do you consider yourself a physically active person?

○ a) Yes

○ b) No

5) Approximately what distance would you travel on foot during the space of a week?

(e.g. 2km equates to approximately 5 laps around a rugby field or 4 laps around the Basin Reserve.)

○ 1) up to 2km

○ 2) between 2km and 5km

○ 3) between 5km and 10km

○ 4) more than 10km per week

6) Do you participate in any individual sporting activities? (e.g. Cycling, Yoga, Swimming, Gym)

○ a) Yes

○ b) No

6a) If Yes, how often do you participate?

○ 1) Every day

○ 2) 2-6 times a week

○ 3) Once a week

○ 4) Once a fortnight

○ 5) Once a month

○ 6) Less than once a month

7) Do you participate in any social team sporting activities?

(e.g. Soccer, Touch Rugby)

○ a) Yes

○ b) No

7a) If Yes, how often do you participate?

○ 1) Every day

○ 2) 2-6 times a week

○ 3) Once a week

○ 4) Once a fortnight

○ 5) Once a month

○ 6) Less than once a month

8) Have you ever participated in any kind of individual 'Extreme' sporting activity? (e.g. Sky Diving, Bungy Jumping)

○ a) Yes

○ b) No

8a) If Yes, did you wear your artificial limb during this activity?

○ 1) Yes

○ 2) No

9) Have you ever broken your artificial limb while participating in any sporting activity ?

○ a) Often
○ b) Sometimes
○ c) Rarely
○ d) Never

10) Do you consider your artificial limb's durability an important issue in everyday usage?

○ a) Yes
○ b) No

11) Does the visual appearance of your artificial limb suit your current lifestyle?

○ a) Yes
○ b) No

12) Are you currently happy with the *overall appearance of your artificial limb*?

○ a) I am very happy with the appearance
○ b) I am happy with the appearance
○ c) It could be slightly improved
○ d) It could drastically improved
○ e) It should be completely changed

13) What do you like best about the visual appearance? (please state briefly)

....

....

....

14) What do you like least about the visual appearance? (please state briefly)

....

....

....

15) *Have you ever been embarrassed in public by what your artificial limb looks like?*

○ a) Always
○ b) Often
○ c) Occasionally
○ d) Rarely
○ e) Never

16) Would you like to comment on the situation?

....

....

....

17) Do you think that the natural shape of your leg should visually be taken into consideration when a new artificial limb is produced for you?

○ a) Yes

○ b) No

18) If an artificial limb looks machine like rather than naturally human, do you think that you may be less willing to use it?

○ a) Yes

○ b) No

19) Do you think that a artificial limb should have the capacity to 'show off' or 'celebrate' your disability?

○ a) Agree

○ b) Disagree

20) Do you think the visual form of current artificial limbs assist or hinder an your rehabilitation?

○ a) Assist

○ b) Neither assist or hinder

○ c) Hinder

21) Do you think a personally customised artificial limb which you have helped to design, will/could ultimately benefit your rehabilitation recovery time?

○ a) Yes
○ b) No

22) In the design of transtibial artificial limbs, functional requirements are given a higher priority than the appearance.

Do you agree or disagree with this statement?

○ a) Agree
○ b) Neither agree or disagree
○ c) Disagree

23) What do you consider to be more important, how well your artificial limb works or what it looks like?

○ a) How it works is more important
○ b) Both the functional and visual aspects should be evenly considered
○ c) How it looks is more important

24) Would you consider an ideal artificial limb product to be one that looks exactly like the missing limb?

○ a) Yes
○ b) No

25) Do you think that an amputee should be able to choose an artificial limb skin colour like their own colour?

○ a) Yes
○ b) No

26) Would you like to be able to choose from a range of skin colours for your artificial limb covering?

○ a) Yes
○ b) No

27) Would you like a choice of graphic patterned options for the visual appearance of your artificial limb?

○ a) Yes
○ b) No

28) Do you find that your artificial limb wears down or catches on the fabric of your clothes?

○ a) Always
○ b) Often
○ c) Sometimes
○ d) Rarely
○ e) Never

29) Do you notice the sound from of your artificial limb during activity?

○ a) Yes

○ b) No

29a) If your answer is Yes please state how obtrusive is this sound during activity?

○ 1) Slightly obtrusive

○ 2) Noticeable

○ 3) Very obtrusive

○ 4) Annoying

○ 5) Unbearable

30) In your opinion should amputees have more access and involvement in the overall design input and features of artificial limbs?

○ a) Yes.

○ b) No

31) Please state your gender.

○ a) Male

○ b) Female

32) Which of these age groups do you belong to?

○ a) 18-24
○ b) 25-29
○ c) 30-39
○ d) 40-49
○ e) 50-59
○ f) 60+ years

If there are any other concerns or comments you would like to mention about the visual appearance of your artificial limb I would very much like to hear about them. Please feel free to add any notes on this page.

....

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APPLIED HUMAN AESTHETIC IN ARTIFICIAL LIMB DESIGN

Daniel Buxton, BDes(Hons).

2005 CONFERENCE ABSTRACT
Industrial Design Department.
Massey University College of Creative Arts.

INTRODUCTION

The term Industrial Design is one not readily recognised in the Prosthetic Artificial Limb industry. A branch of industrial design is that of 'human interface' application to product design and development.

The applied human aesthetic or natural volume and form in transtibial artificial limb design, currently seems to maintain an inconsistent commmunion with it's respective functional objectives. Technical advancements in artificial limb research and development are at the forefront in robotic industries, material development and interface systems, hence function currently dominates form. Human-machine interactions or product interfacing contains various factors that produce outcomes such as physiological expectations and requirments. An amputee's personal identity and social interaction, are reflected in the interface qualities of themselves and their ability to communicate with their artificial limb(s).

I therefore suggest that by applying Industrial Design to the form of a transtibial artificial limb, we may improve an amputee's recovery rehabiltation time.

CENTRAL PROPOSITION

The central proposition or key idea for this study is to design, develop and prototype an exo-skeletal transtibial (below knee) artificial limb incorporating a suggested 'Applied Human Aesthetic' methodology. This study sets out to define transtibial amputees' aesthetic values associated with their personal ideals of their artificial limb(s).

PROJECT AIMS

The following lists the project aims:
- Identify basic humanistic aesthetic issues, transtibial amputees associate with their artificial limb via a qualitative questionnaire.
- Apply a suggested 'Applied Human Aesthetic' design methodology to the design and development of a transtibial artificial limb.
- Design, develop and prototype a zip on transtibial sectioned exo-skeletal artificial limb.
- Implement material based research and development study, incorporating laminate composite fabrics, memory alloy mesh and zip attachments.

RESEARCH OBJECTIVES

The following lists the industrial design research objectives:
- Identify transtibial amputee's personal aesthetic ideals regarding their artificial limb via a qualitative questionnaire.
- Incorporate 'Applied Human Aesthetic' methodology in a transtibial artificial limb design.

DESIGN DEVELOPMENT OBJECTIVES

The following lists the industrial design development objectives:
- Design and develop exo-skeletal transtibial artificial limb blueprint that is based on the human natural form.
- Design and develop a conceptual zip on attachment (suspension) system.
- Undertake a composite fabric, alloy mesh laminate materials research.

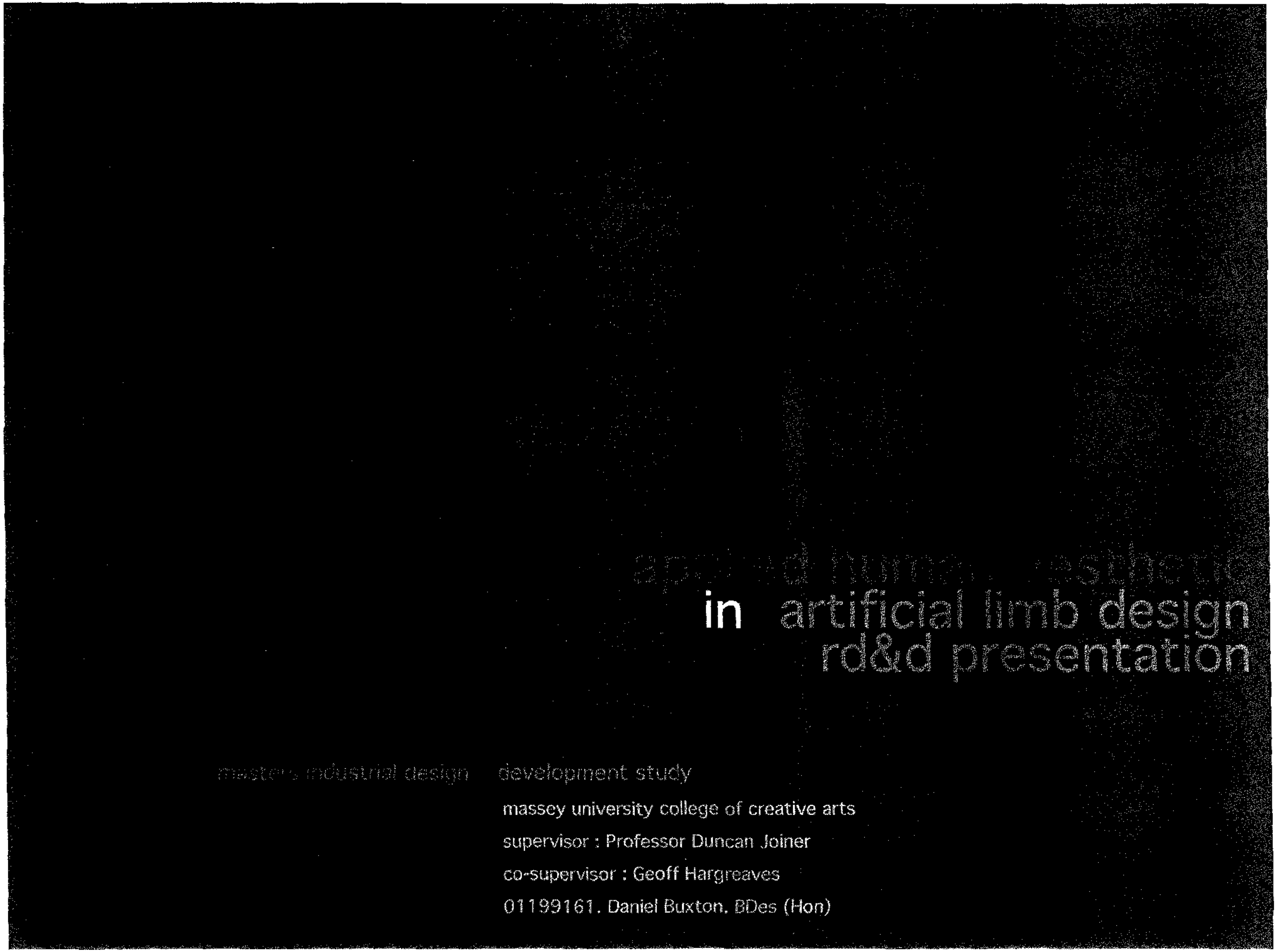
PROJECT GOALS

The design and development goals for this project are to refine and create a tibial sectioned artificial limb that:
- incorporates an exo-skeletal design that replicates natural form;
- co-exists with predefined functions, attachments and robotic developments;
- replicates a natural kinetic return during the walking phase;
- incorporates a zip up attachment system with breathable liner.

INITIAL CONCLUSIONS AND RECOMMMENDATIONS

Some initial conclusions and recommendations from this study are:
- The application of a 'AHA' methodology as an artificial limb product design point of departure.
- Inclusion of industrial design practice during the research and development in the prosthetic industry.
- Involve amputees during the design process.
- Include amputee comfort factors during research and development.

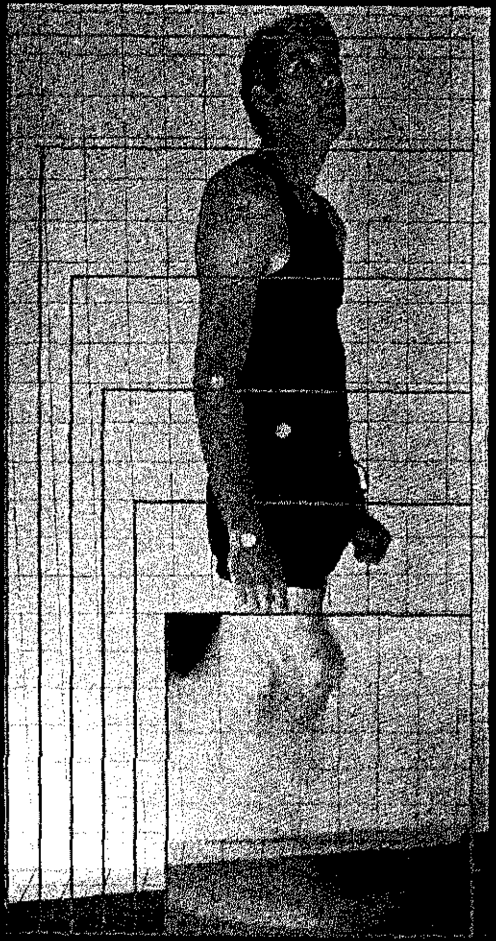
International Society Prosthetics and Orthotics Poster Presentation. Hong Kong, 2004.
Recipient of the 2005 Wellington City Council Creativity and Innovation Scholarship.
Invitation to present at the 2006 New Zealand Prosthetics Orthotics Conference, Wellington.



applied human aesthetic
in artificial limb design
rd&d presentation

masters industrial design development study

massey university college of creative arts
supervisor : Professor Duncan Joiner
co-supervisor : Geoff Hargreaves
01199161. Daniel Buxton. BDes (Hon)



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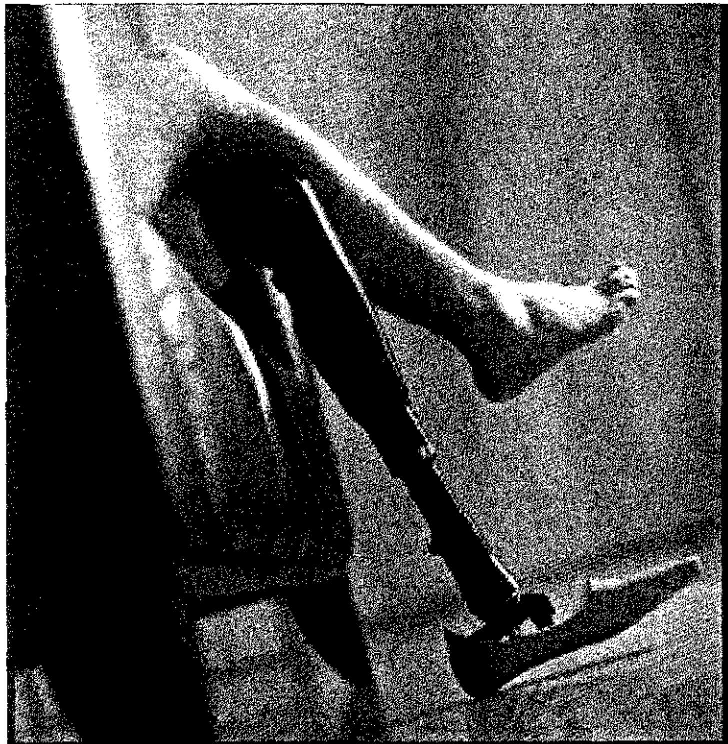
in artificial limb design

the transtibial artificial limb



"form follows function - that has been misunderstood."

"Form and function should be one, joined in a spiritual union."

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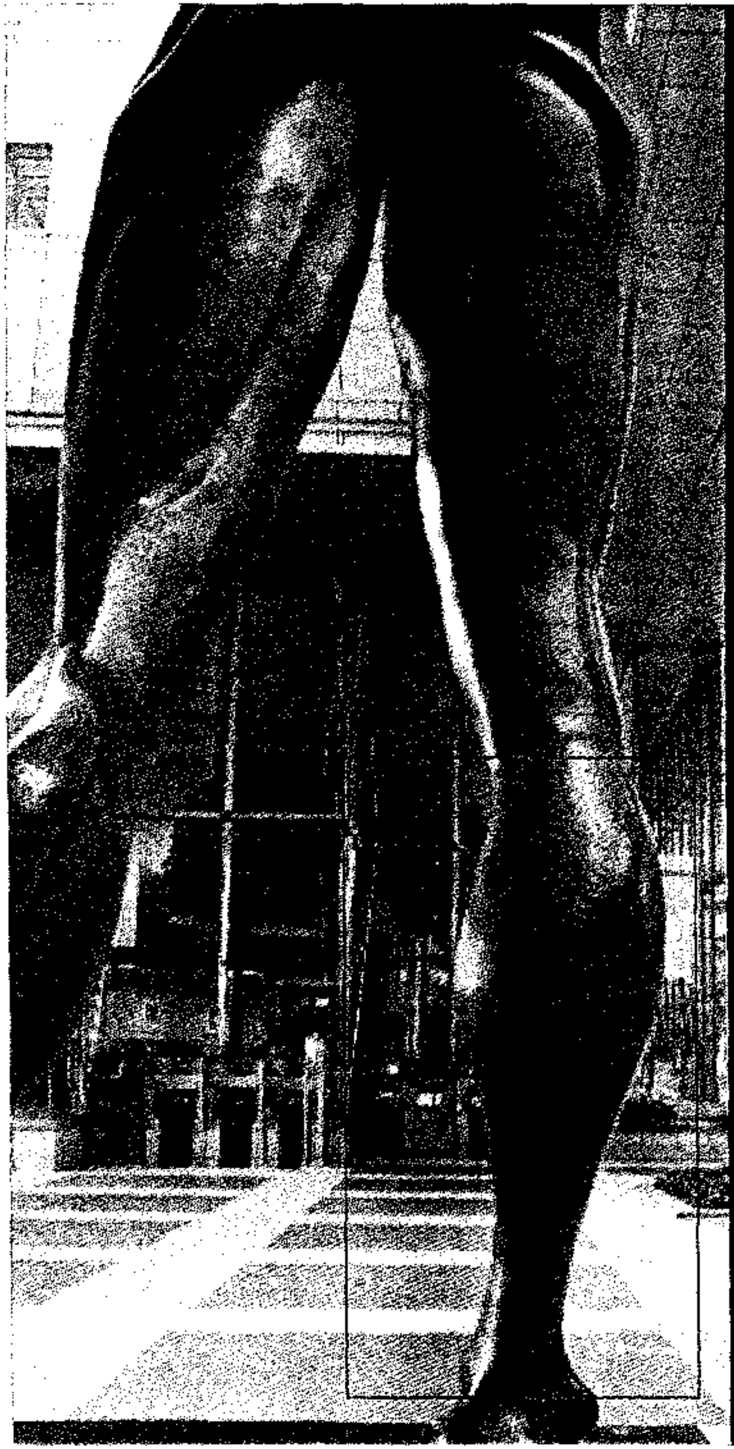


A branch of industrial design is the application of *'humanistic factors'* to product development and design.

Current *'state of the art'* artificial limb forms, seem to provide an inconsistent humanistic communion with the coinciding functional attributes.

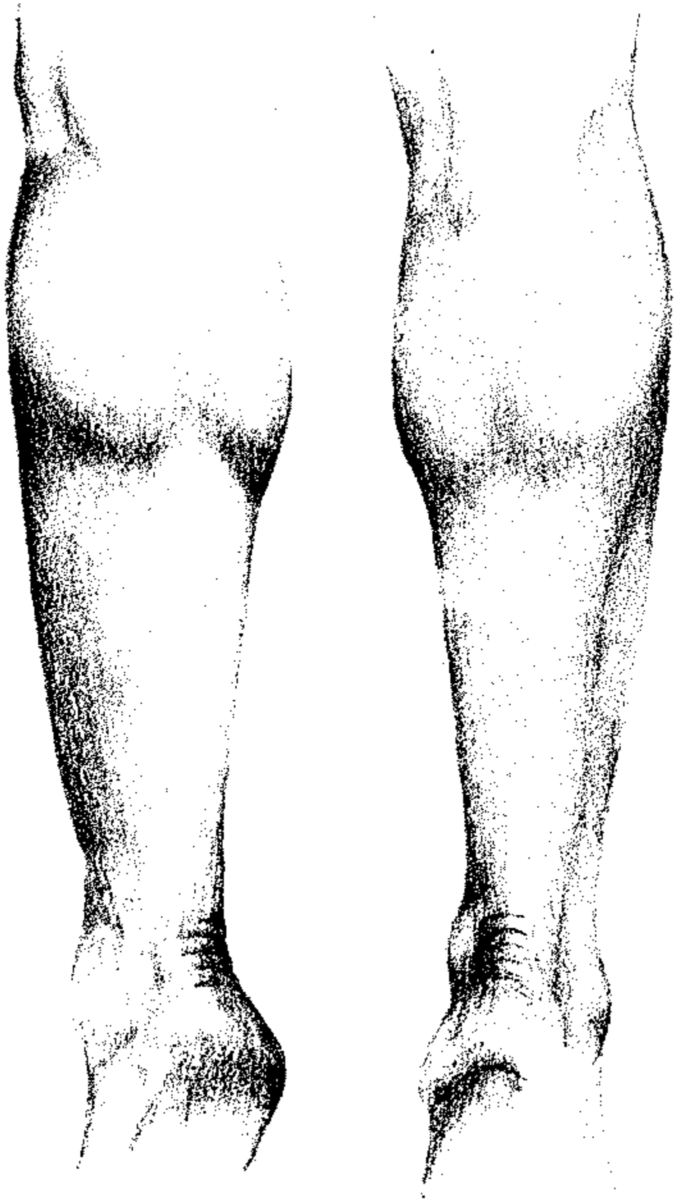
Transtibial amputee physiological preferences towards their artificial limb(s) suggests the functional attributes improves their rehabilitation recovery processes.

abstract

Can we therefore suggest that if a humanistic form or an *'Applied Human Aesthetic'* is applied via the design process, to the structural architecture of a transtibial artificial limb, the rehabilitation recovery processes may well be improved exponentially?

“Why don’t we make artificial limbs that are not stumps or broomsticks?”

James Coe.



- the central proposition or (key idea) of this industrial design masters study is to design, develop and prototype a transtibial (below knee) artificial limb, utilising a suggested *'Applied Human Aesthetic'* design development methodology.

[This design development study is a continuation from the undergraduate research study 'The Artificial Limb' BDes (Hon) completed in 2003 at Massey University School of Design, Fine Arts and Music, Wellington, New Zealand.]

central proposition

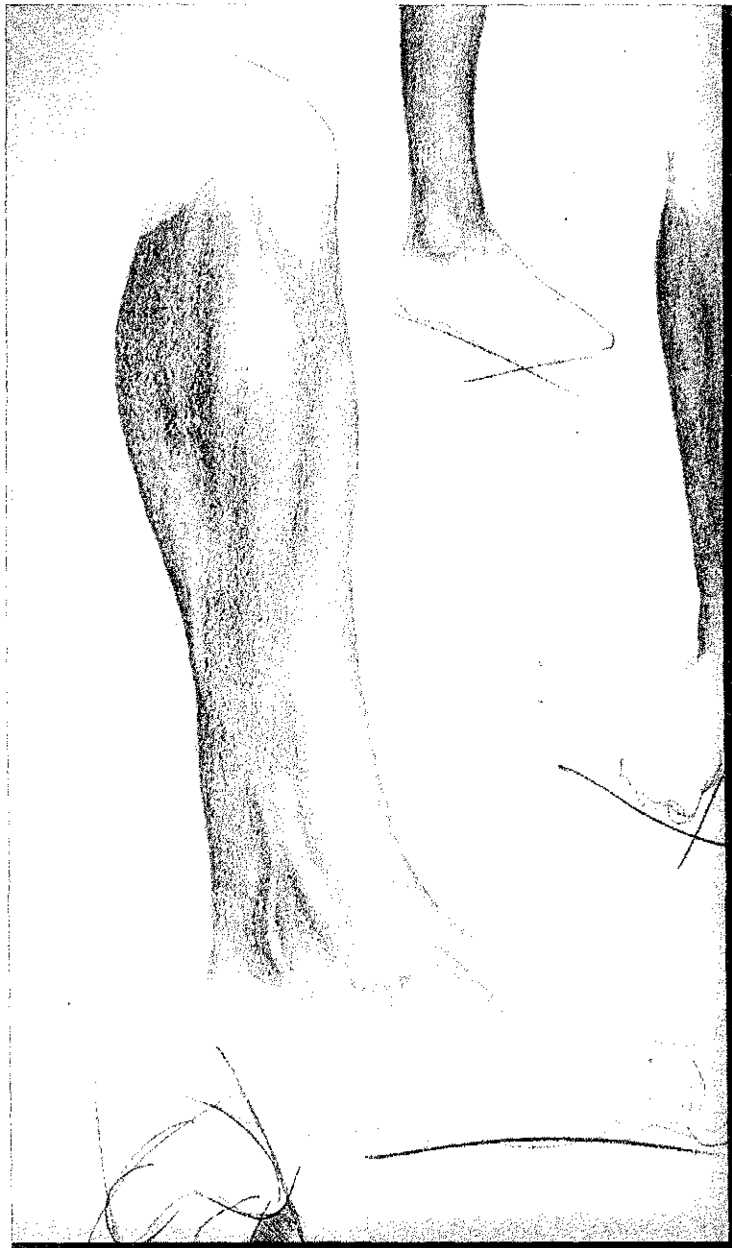
"We've got to this international place *in the world and I think that if we are going to do anything in New Zealand in the way of design, we have to first become jolly good designers."*

James Coe.

"Possibly we should produce international artificial limbs *and Maori artificial limbs."*

Ian Athfield.

an applied human aesthetic?

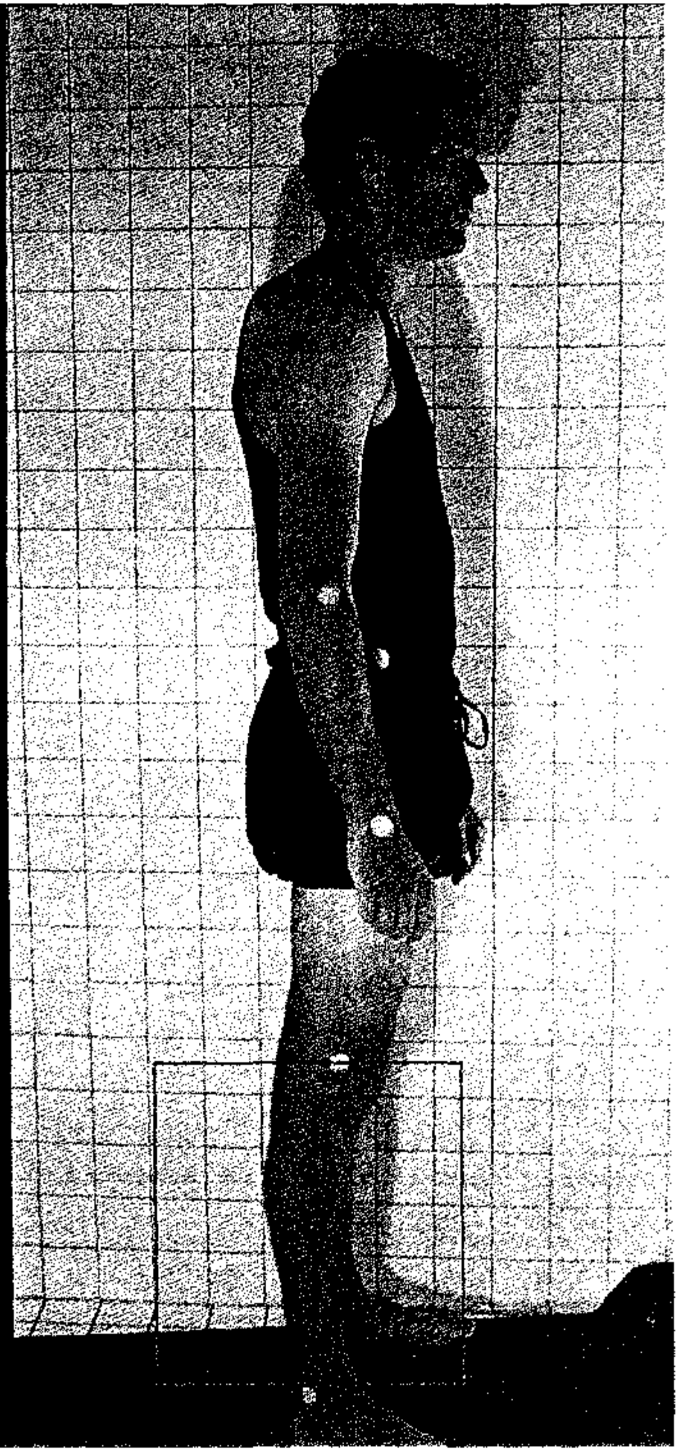


aim

- identify basic humanistic aesthetic issues, transtibial amputees identify with their artificial limb(s) via a qualitative questionnaire;
- apply a suggested *"APA"* methodology to the transtibial exo skeleton artificial limb design development;
- design and develop a zip on transtibial sectioned exo skeleton artificial limb that applies an amputees personalised human form without jeopardising functional dynamics;
- implement a material based development study to identify suitable laminate composites and memory alloy mesh combinations;
- design and develop an outer stocking artificial skin layer.

the transtibial artificial limb:

- co-exist with all standardised functional attributes
- cohesion with state of the art product applications
- marketable product
- conform to existing residual limb molding techniques
- accessible manufacture and production criteria
- product servicing requirements
- low production application costing



industrial design development objectives

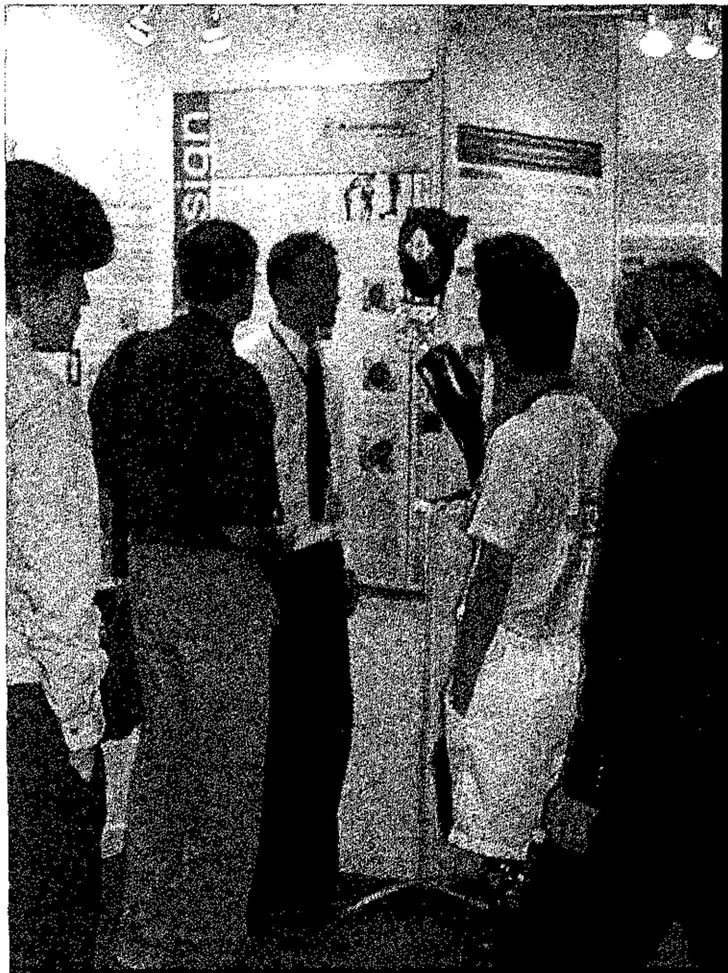
- develop a conceptual zip on a operational attachment (suspension) system
- develop a breathable residual limb environment
- develop a transtibial exo skeleton blueprint design
- develop carbon fiber, memory mesh alloy lamination
- prototype a transtibial artificial limb

industrial design research objectives

- define active transtibial amputees artificial limb personal aesthetic ideals via qualitative questionnaire
- apply an Applied Human Aesthetic methodology to a transtibial artificial limb design development

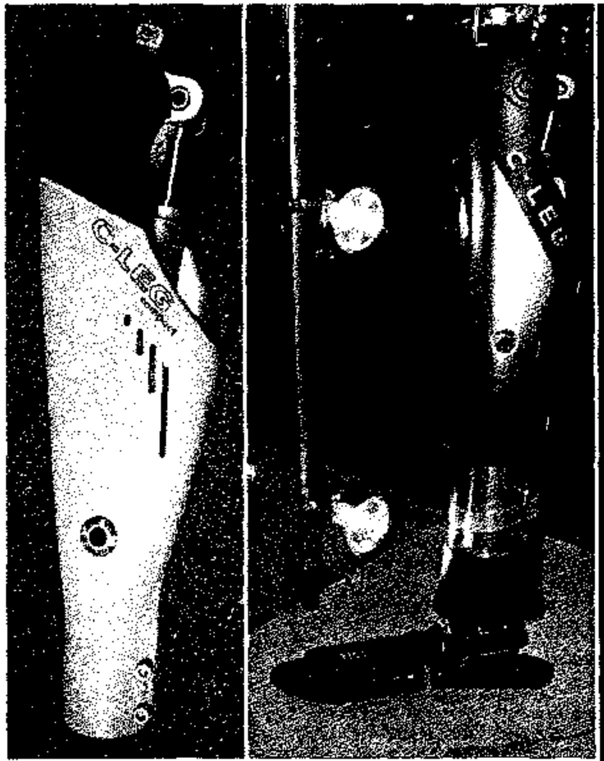
Kate Horan transtibial paraolympian amputee

transtibial amputee research



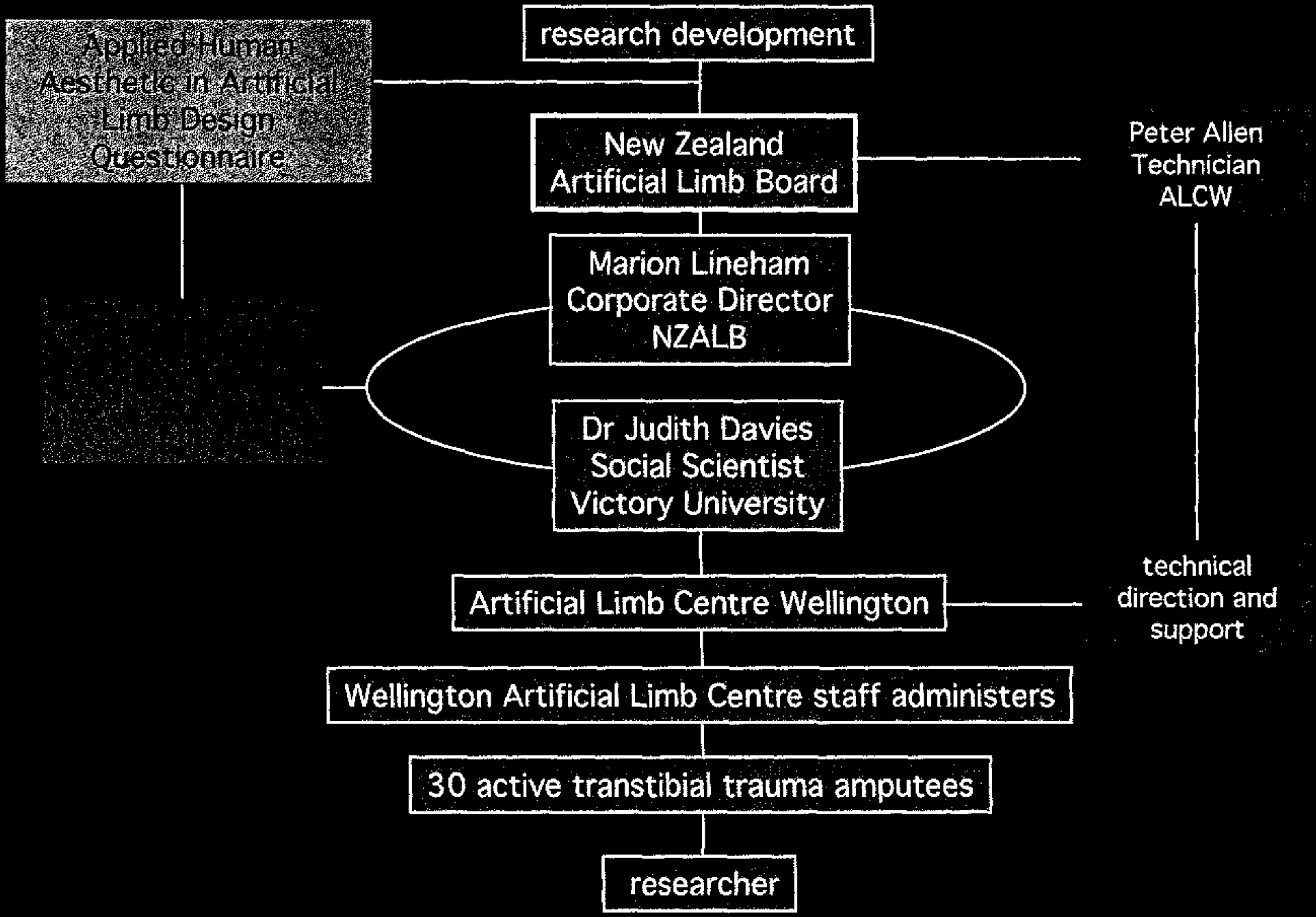
initial design concept feedback

- ISPO Hong Kong 2004. initial specialist market feedback from tradeshow was very exciting
- product form created lots of attention
- attending experts and amputees expressed interest in the humanistic design
- working prototype was requested by both INDUSTRY and amputee public



state

- current '*state of the art*' artificial limb product is driven by functionality
- it takes up to *15* years for a high end product to surpass the breakeven benchmark
- amputee clinical testing can take up to a period of 5 years before product market launch



Applied Human Aesthetic in Artificial Limb Design Questionnaire

research development

New Zealand
Artificial Limb Board

Peter Allen
Technician
ALCW

Marion Lineham
Corporate Director
NZALB

Dr Judith Davies
Social Scientist
Victory University

technical
direction and
support

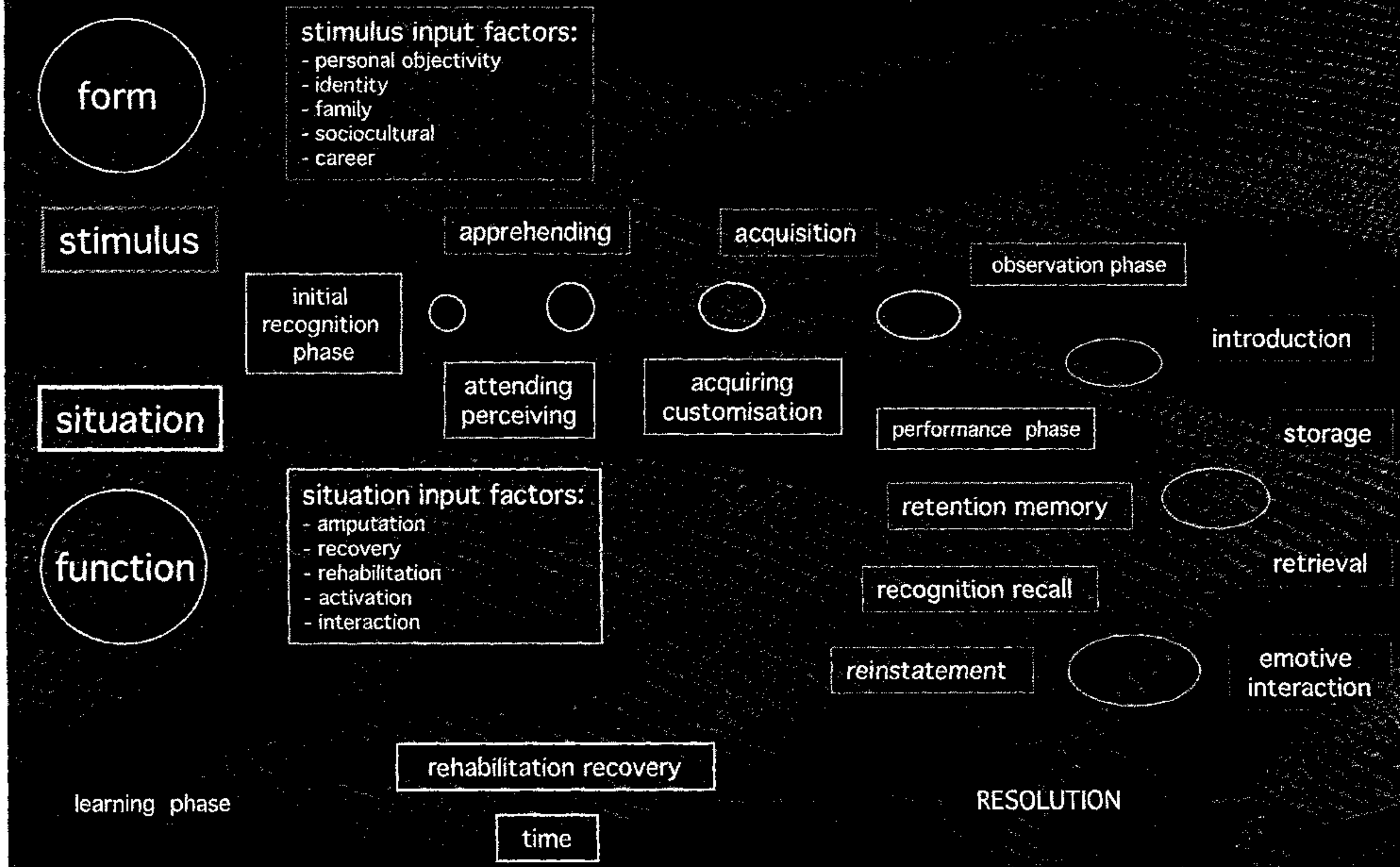
Artificial Limb Centre Wellington

Wellington Artificial Limb Centre staff administers

30 active transtibial trauma amputees

researcher

qualitative research feeder system network



form

stimulus input factors:
- personal objectivity
- identity
- family
- sociocultural
- career

stimulus

apprehending

acquisition

observation phase

initial recognition phase

introduction

situation

attending perceiving

acquiring customisation

performance phase

storage

situation input factors:
- amputation
- recovery
- rehabilitation
- activation
- interaction

retention memory

function

retrieval

recognition recall

reinstatement

emotive interaction

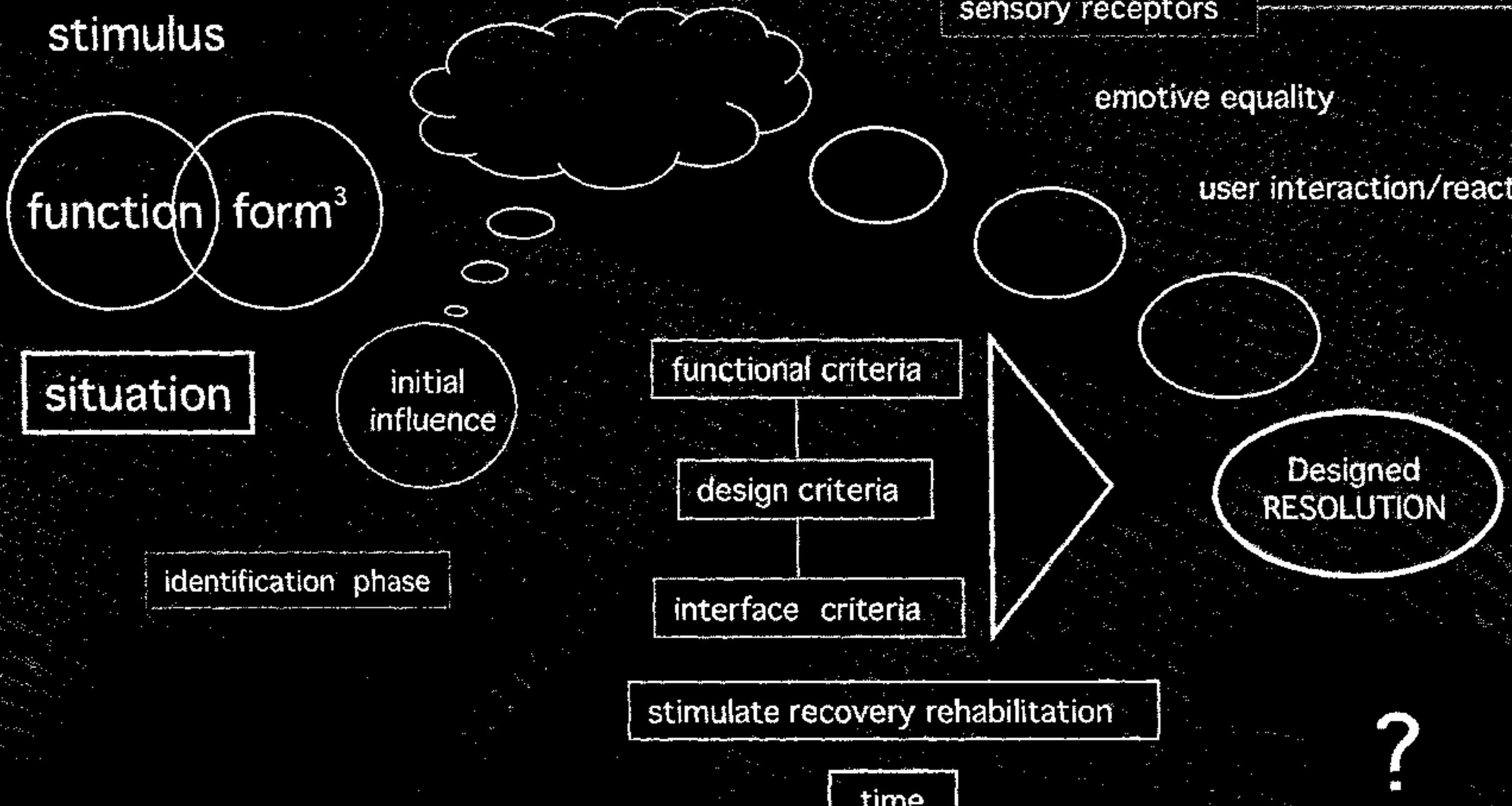
rehabilitation recovery

learning phase

RESOLUTION

time

amputee artificial limb product event learning sequence



design source

sensory phase

object transmitter

sensory receptors

stimulus

emotive equality

function form^3

user interaction/reaction

situation

initial influence

functional criteria

design criteria

interface criteria

Designed RESOLUTION

identification phase

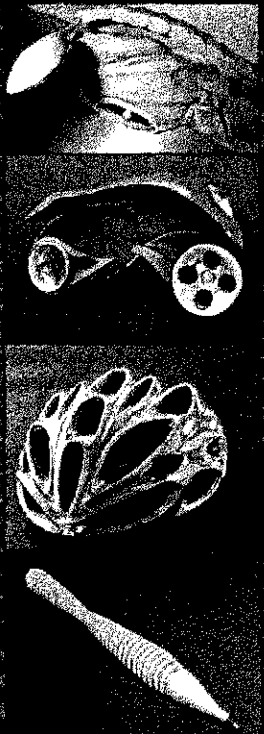
stimulate recovery rehabilitation

time

?

industrial design artificial limb product rd&d methodology

Who would want it?
Why would they want it?



designed product
-gothic influences
-visual appreciation
-self fulfillment

wow factor

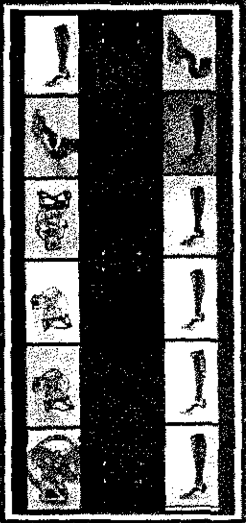
performance
-functional criteria

physical
-utility attributes

balance
-form/function

ergonomics
-customisation

behavioral factor



sociology
-branding
-product identification

look-feel
-interactive

cultural
-personal identity

sociometry
-group relationships

reflective factor

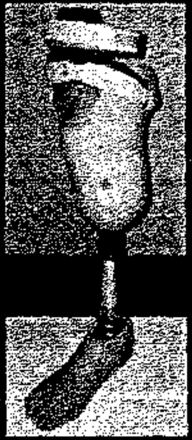
industrial design artificial limb rd&d product optimisation

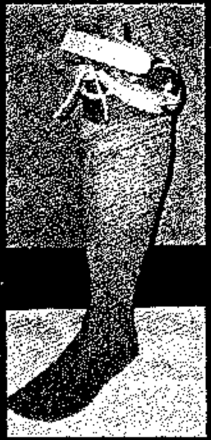
irritating
repulsive
annoying

arousing

sensational
engaging
exciting

displeasing
unattractive





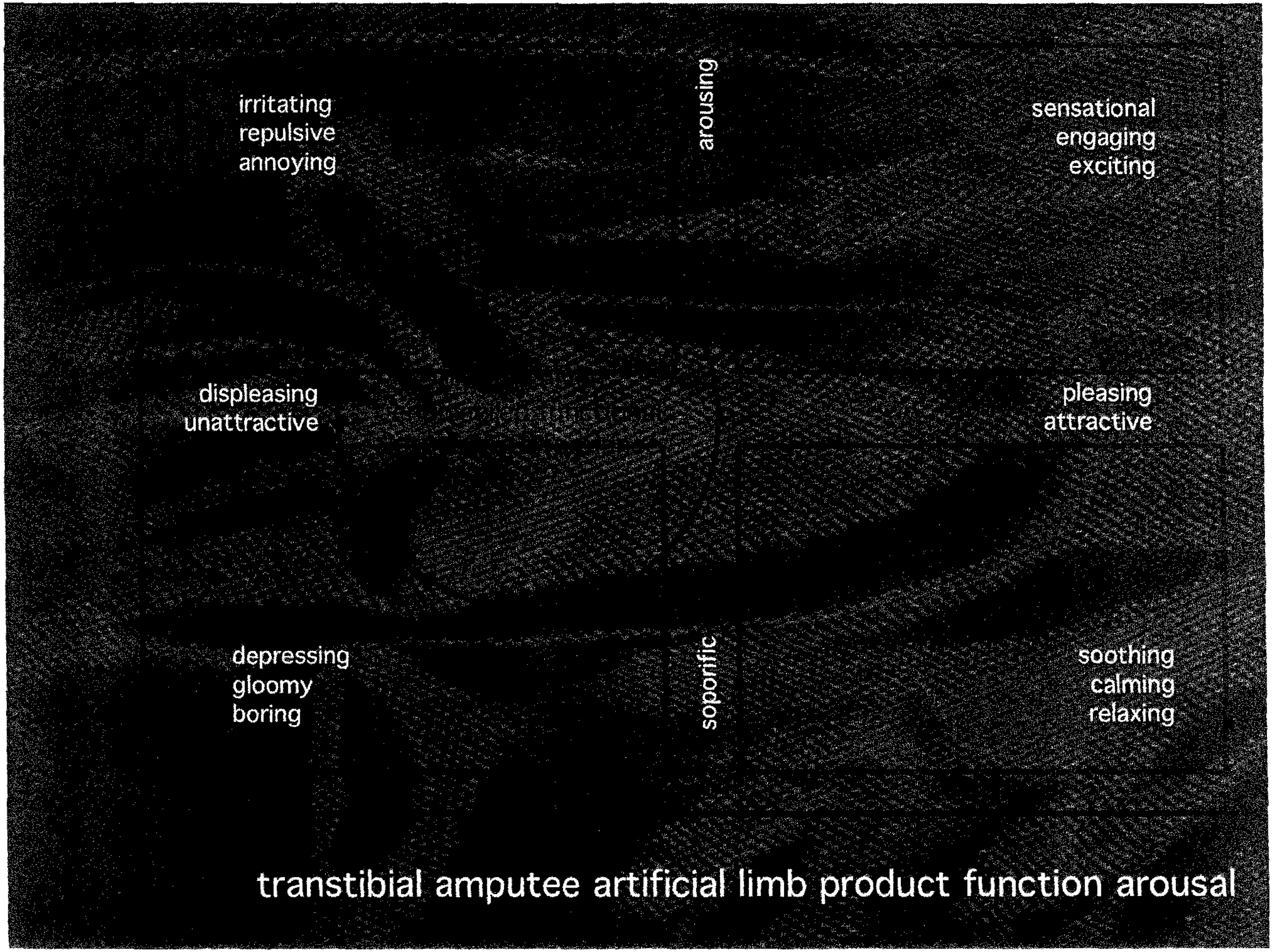
pleasing
attractive

depressing
gloomy
boring

soporific

soothing
calming
relaxing

transtibial artificial limb product form arousal



irritating
repulsive
annoying

arousing

sensational
engaging
exciting

displeasing
unattractive

pleasing
attractive

depressing
gloomy
boring

soporific

soothing
calming
relaxing

transtibial amputee artificial limb product function arousal

irritating
repulsive
annoying

arousing

sensational
engaging
exciting

displeasing
unattractive

pleasing
attractive

depressing
gloomy
boring

soporific

soothing
calming
relaxing

transtibial amputee artificial limb product function arousal

irritating
repulsive
annoying

arousing

sensational
engaging
exciting

displeasing
unattractive

transtibial artificial limb
designed product form

soporific

depressing
gloomy
boring

soothing
calming
relaxing

transtibial amputee artificial limb product form arousal

irritating
repulsive
annoying

arousing

transtibial artificial limb
functionally engineered
designed formed product

displeasing
unattractive

pleasing
attractive

depressing
gloomy
boring

soporific

soothing
calming
relaxing

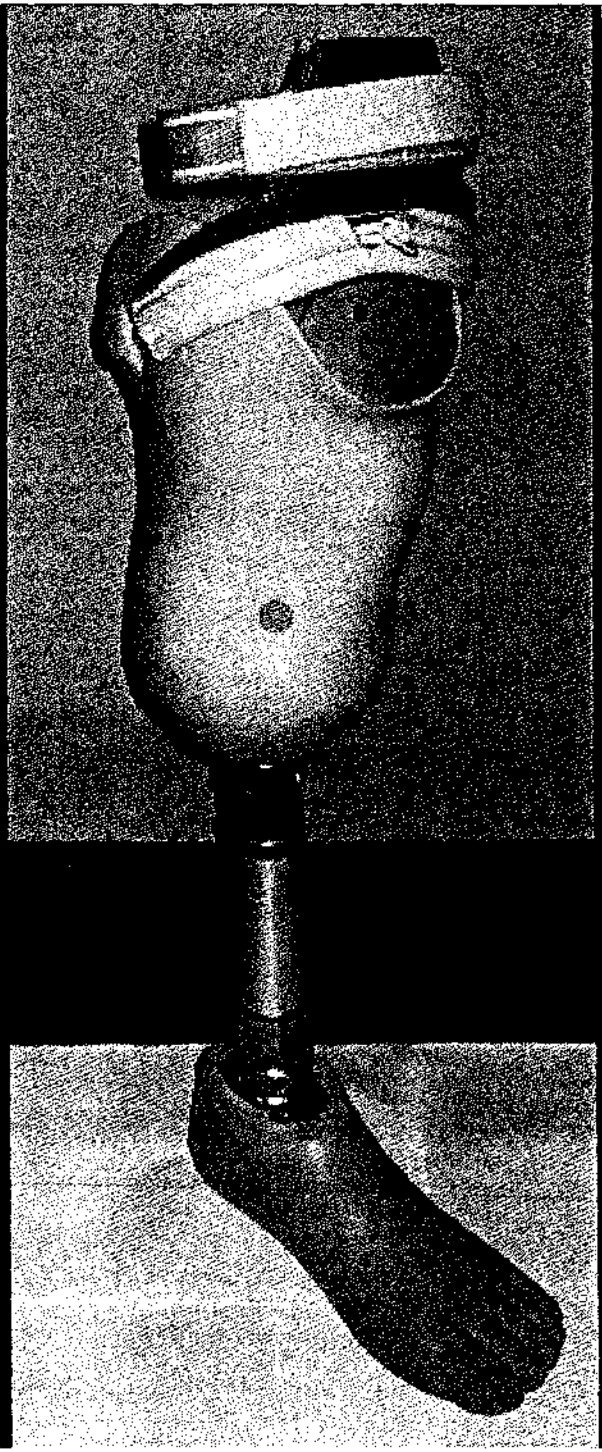
transtibial amputee artificial limb product form arousal

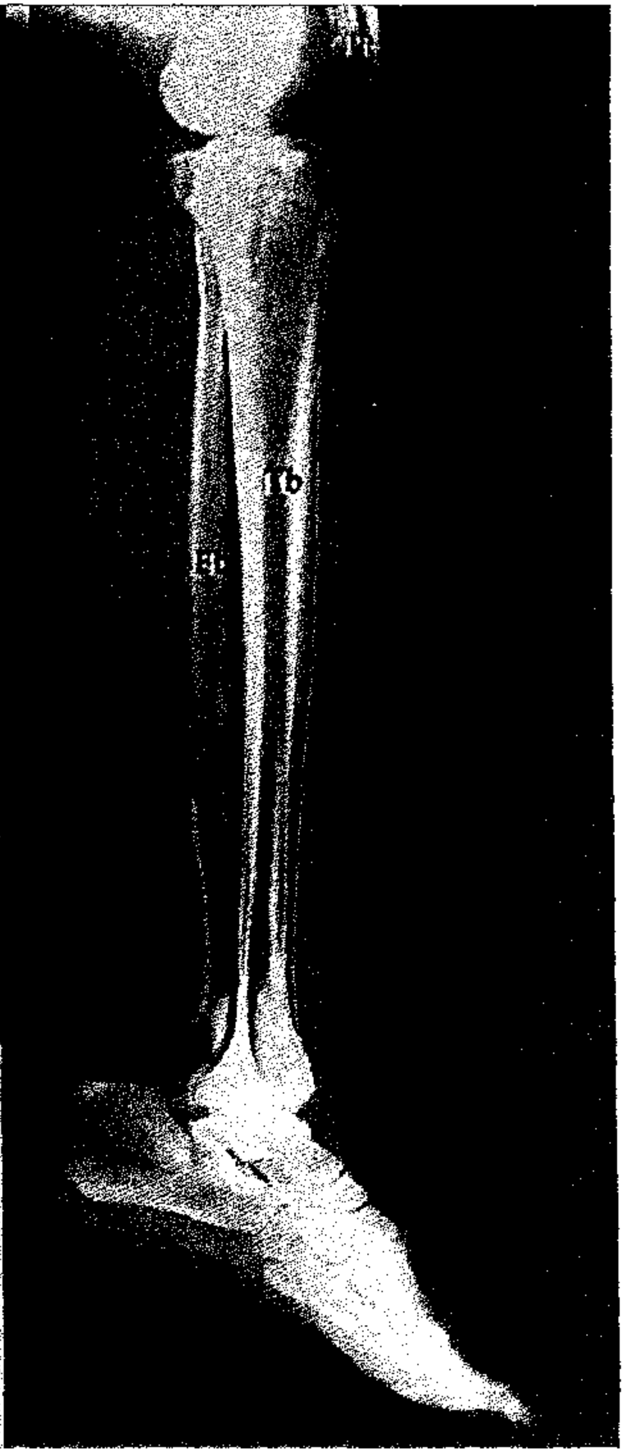
- current transtibial artificial limb architecture uses an endo structural design

(Tb) tibia: load bearing bone of lower leg.

(Fb) fibula: not load bearing, muscle attachment bone

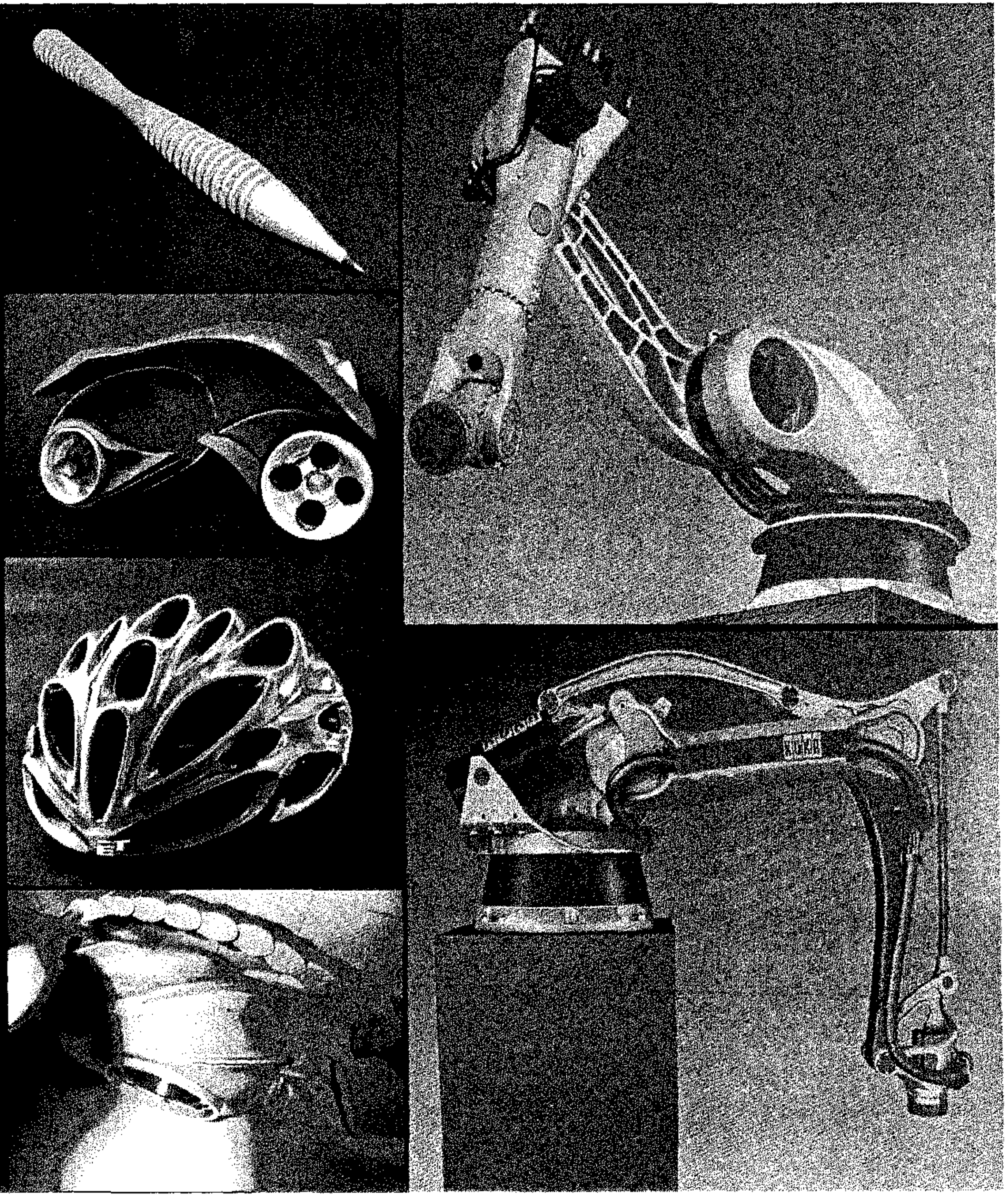
endo architecture





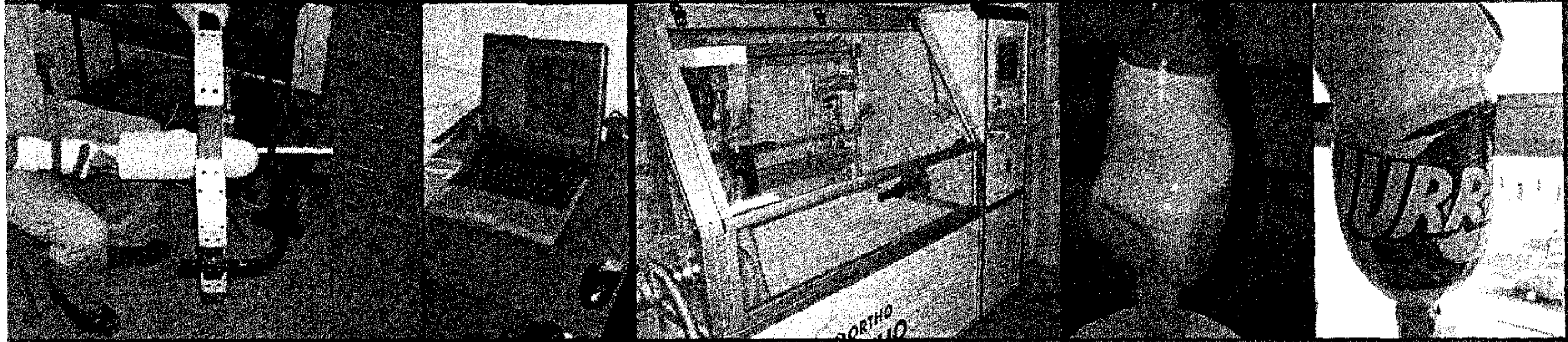
- exo product architecture derives from a gothic style of buildings such as the British Parliament Buildings

exo architecture



- negative molding from existing limb 3D scanner
- positive residual form mold rapid prototype
- positive vacuum carbon glass matting
- applied finishing techniques user customisation

current production manufacture



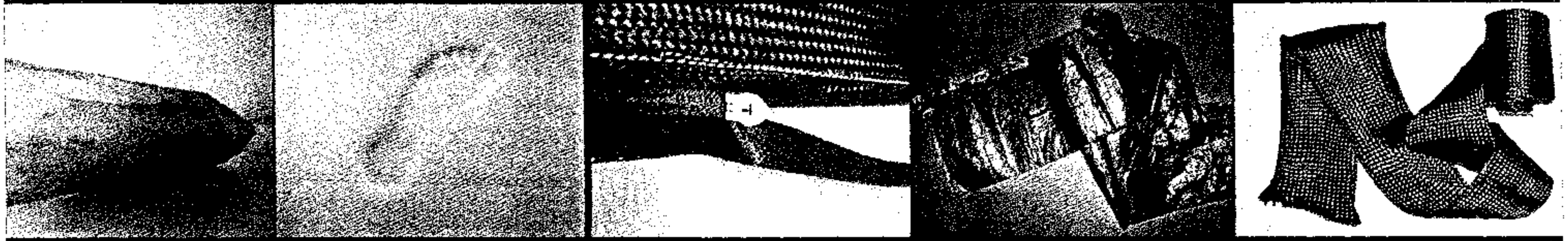
material

primary material group

- carbon fabric stocking
- memory alloy mesh
- memory breathable foam
- YKK waterproof zip
- cuban fiber teflon fabric

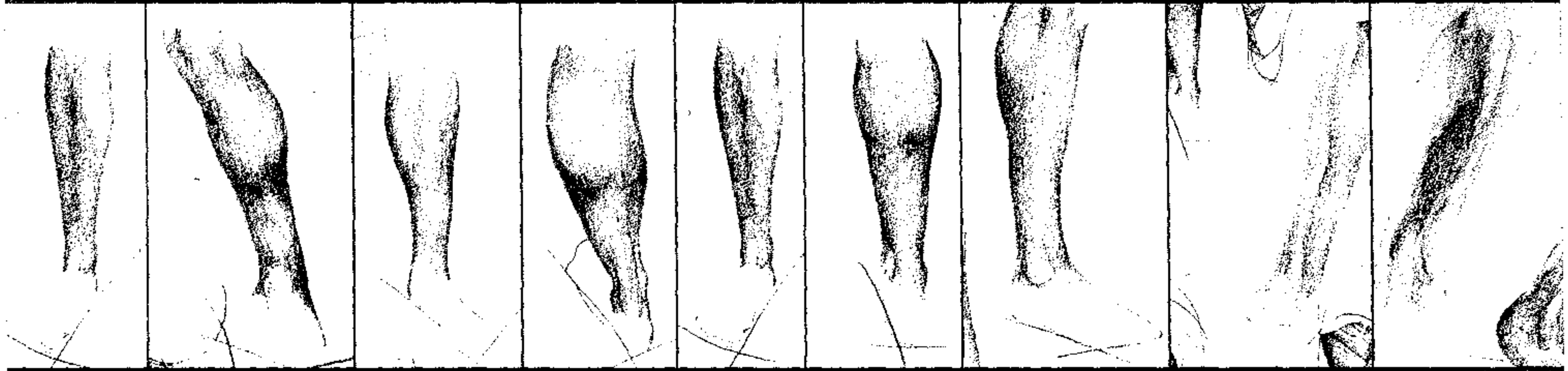
secondary material group

- textilium aluminised glass
- latex silk stocking



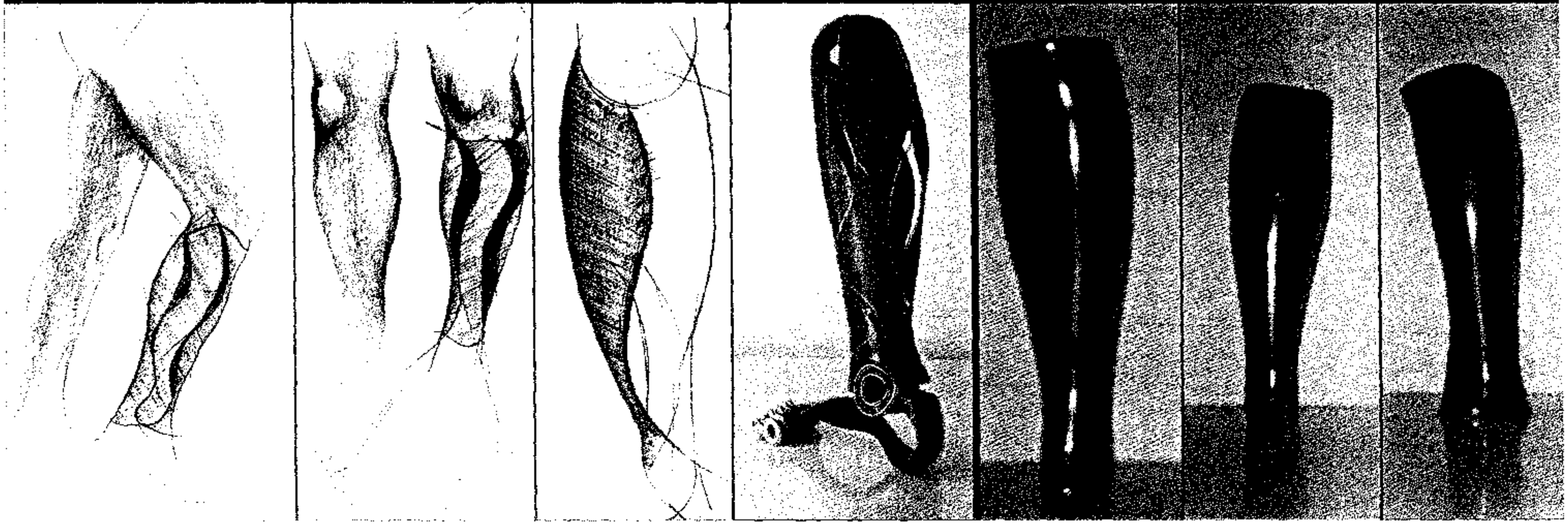
- ergonomic study and identification of the various muscle groups in the tibial region is required to define a basic design aesthetic for visual product point of departure

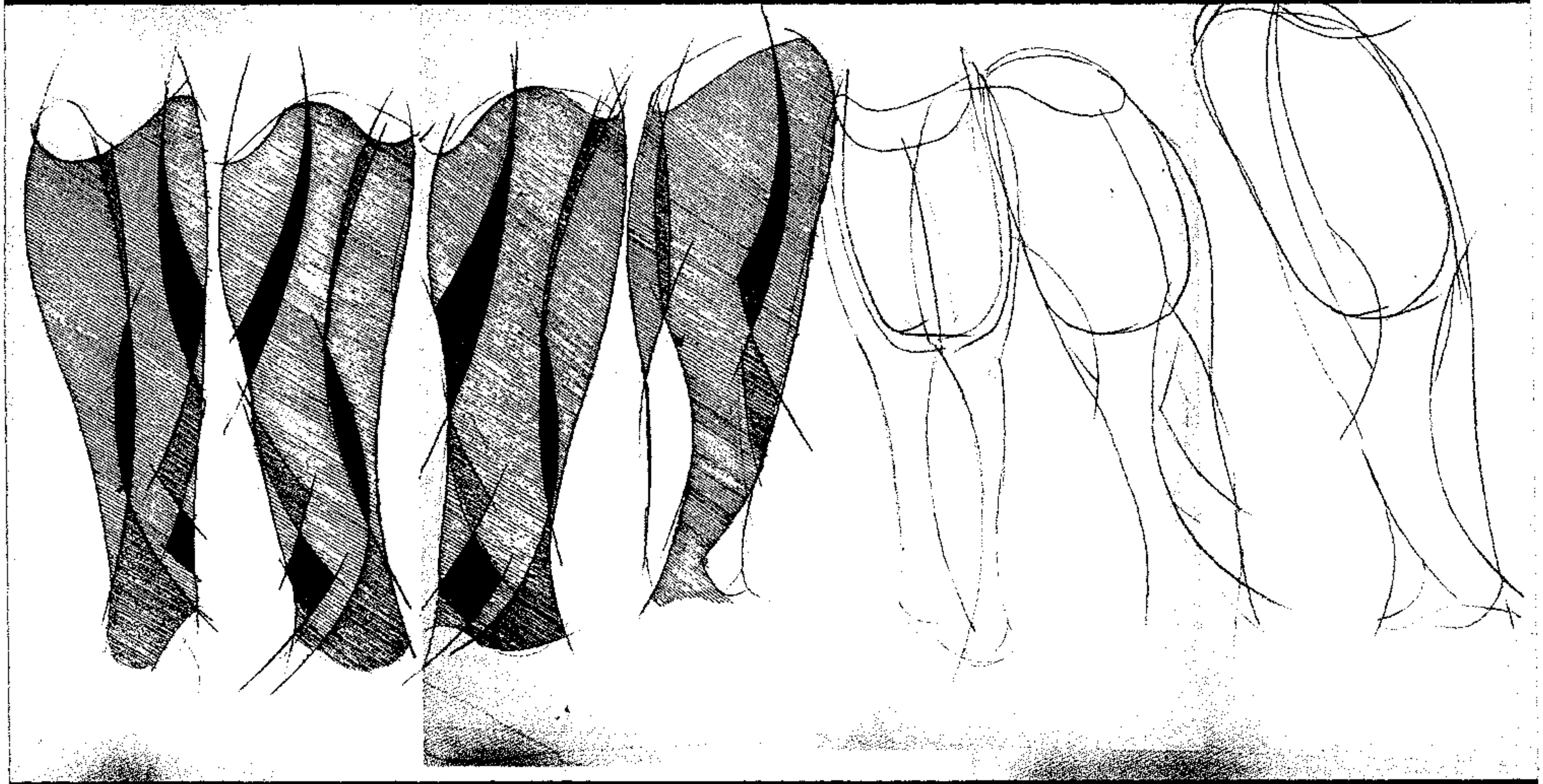
ergonomic



- concept design ideas are based on replicating localised muscle group form and to a certain extent action thus forming an exo skeleton shell that can provide basic kinetic return during dynamic movement phase

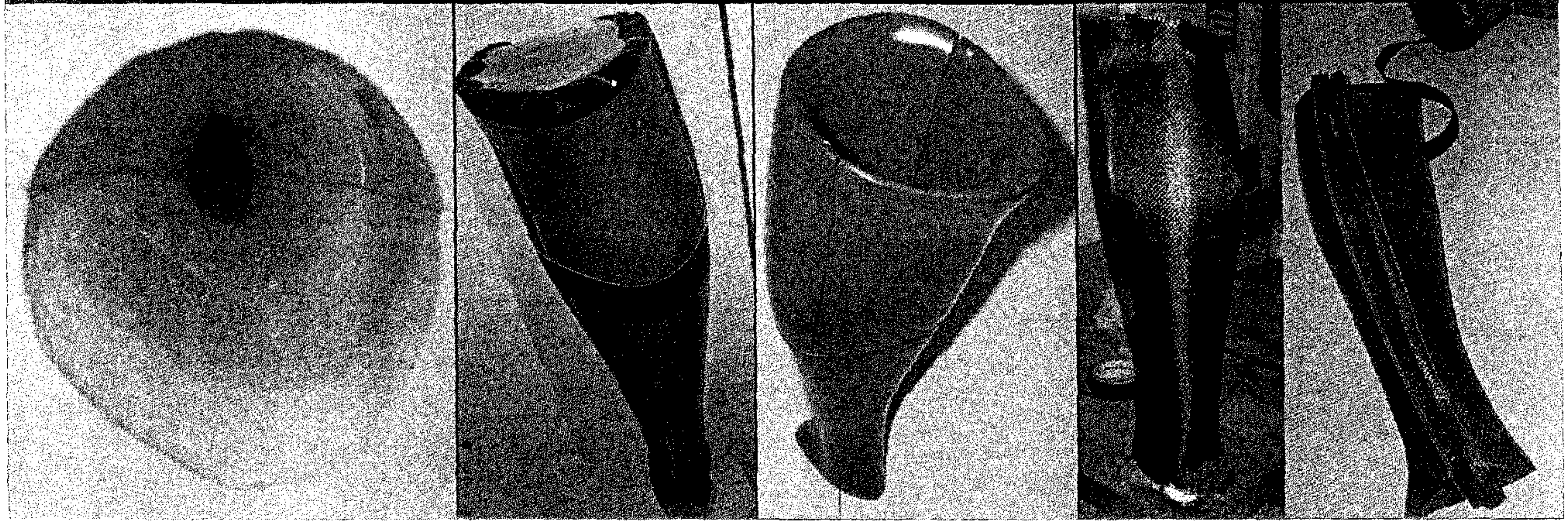
concept development





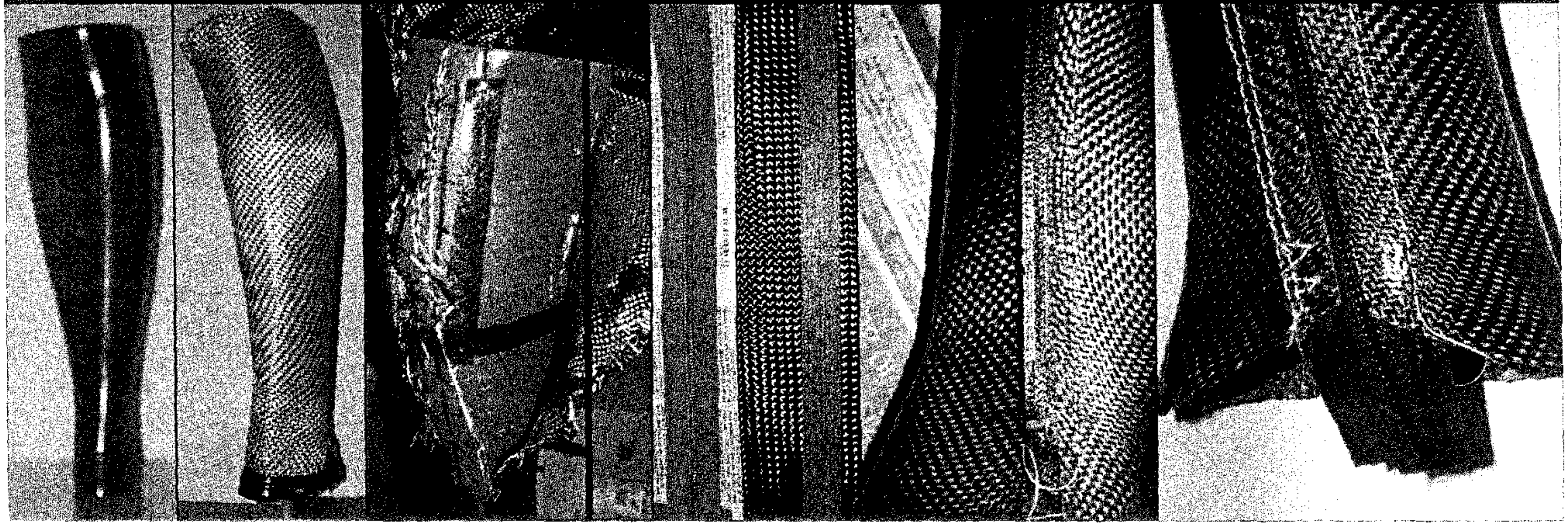
- *the residual limb mold* is first cast
- negative leg casts are then made to form a full size positive transtibial mold
- the completed positive mold then is wraped with the carbon stocking and set
- once removed from mold the zip is embedded in the exo shell

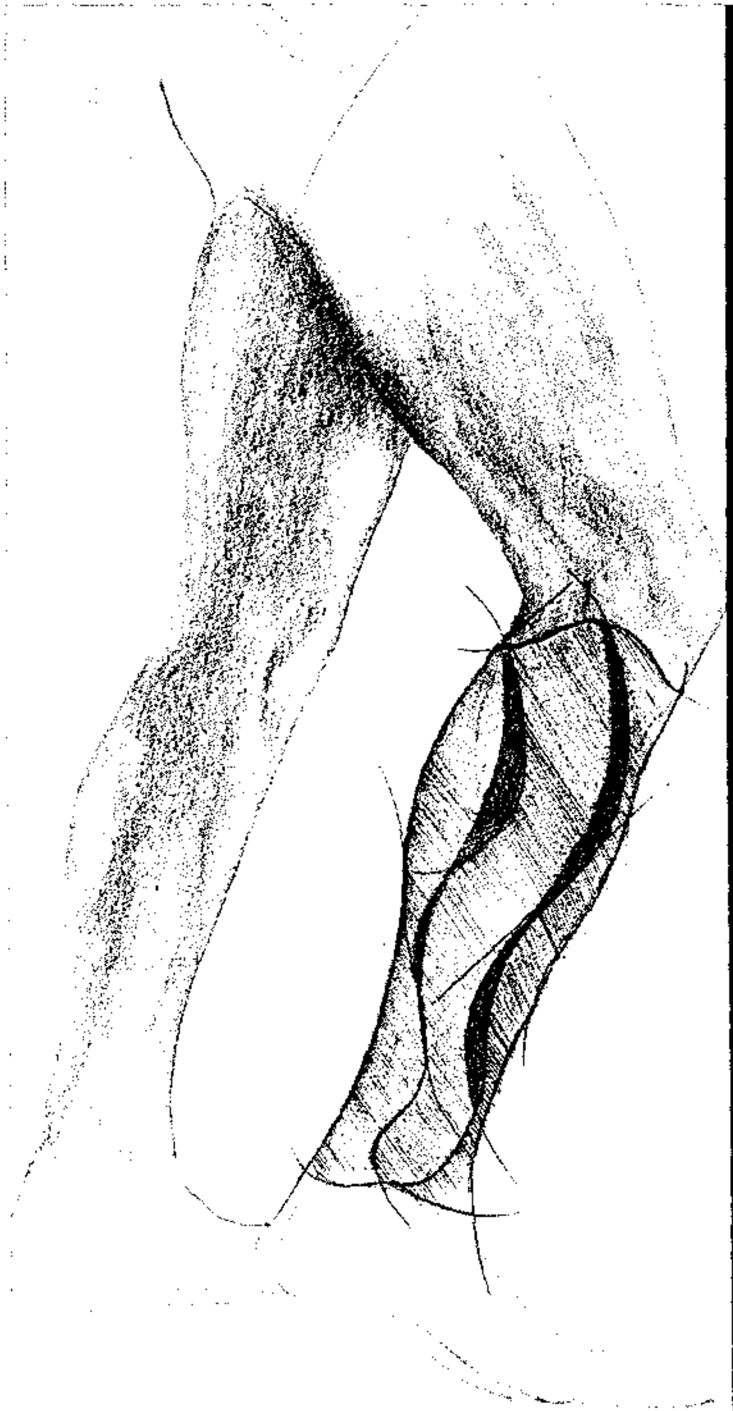
prototype molding design development



- early prototyping revealed problems with mold release agents partly destroying the mold as the exo shell was removed
- the attachment of the zip to the carbon exo shell also required a different approach

prototyping design development





initial conclusion

-application of a AHA methodology as a product foundation point of departure in the design and development of transtibial artificial limbs
- inclusion of design practice into engineered dominated industry
- involvement of amputee in design process
- inclusion of amputee comfort factors during research and development stages

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[illegible]?

The 11th World Congress of the International Society for Prosthetics & Orthotics
1-6 August 2004, Hong Kong Convention and Exhibition Centre, Hong Kong

Artificial Limb Industrial Design.
Applied Human Aesthetic in artificial limb design.

Daniel Buxton. BDes (Hnrs).
Massey University School of Industrial Design. Wellington. New Zealand.

Introduction.

The term 'Industrial Design' is one that will be not be readily recognised within the Prosthetic industry.
A branch of Industrial Design is the application of 'humanistic factors' to product development and design. Applied Human Aesthetic (AHA) in artificial limb design currently seems to provide an inconsistent communion with visual, comfort and interface aspects in today's artificial limb design, with regard to the physiological expectation and requirements of an amputee and their personal identity. In relation, current technical advancements in artificial limb research and development are at the fore front of robotic industries, material development and to a varied extent man/machine interface systems.

Aim.

To development a transfemoral artificial limb model that incorporates the 'Applied Human Aesthetic' methodology in design and development, without effecting the intended function.

Goal.

To design and develop an artificial limb model that maintains the current suggested state of the art functional systems while incorporating the 'Applied Human Aesthetic' methodology it's it design.

Methodology.

The AHA methodology was applied to the design and development of a humanistic based transfemoral artificial limb model. An existing 'state of the art' transfemoral artificial limb was analysed to determine functional capabilities. The replication of human motion capacity through computer simulation, combined with product data analysis and the study of human motion via kinetosphereic ergonomic processes, human motion dynamics and limitations defined the applied human aesthetic functional boundaries. A study of the relevant human muscle groups combined with material and processes research was undertaken to determine the current market availability of 'state of the art' materials required to achieve muscle group replication.

Conclusion.

The final design model used a carbon kevlar/fibre and nitinol alloy, laminated together and shaped around predefined muscle groups. These fins were combined together to form a semi functional femoral and tibial exo skeleton. The application of a U.V dependent coloured silicon skin over the exo skeleton completed the model. While functional capabilities were uninhibited, through the process of 'Applied Human Aesthetic' methodology, individual and ethnic identity, human form, functional interface extension and physiological aspects can be addressed.

Figure 1:
A transfemoral artificial limb prototype that incorporates 'Appiled Human Aesthetic' in it's design and development methodology.

Design and developemnt by
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2005 Celebrating Research Day
Applied Human Aesthetic in Artificial Limb Design

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Introduction

A branch of industrial design is that of 'human interface' application to product design and development. The applied human aesthetic or natural volume and form in current transtibial artificial limb design, seems to maintain an inconsistent communion with its respective functional objectives. An amputee's personal identity and social interaction are reflected in the interface qualities of themselves and their ability to communicate with their artificial limb(s). The design aesthetic, or interface stimulus, applied to a transtibial (below knee) artificial limb should have an ability to reflect an amputee's personal taste, identity and culture. The design aesthetic of transtibial artificial limbs *currently reflects high engineered* function (State of Art).

The Central Proposition of the research design and development study is to prototype an exo-skeletal transtibial artificial limb that incorporates a suggested Applied Human Aesthetic methodology. A designed visual aesthetic maintaining natural form and functional attributes can be obtained using composite fabric, *alloy mesh laminations.*

Project Aims

- Identify aesthetic issues that transtibial amputees associate with their artificial limb(s).
- Apply an 'Applied Human Aesthetic' methodology to the design of an exo-skeletal *artificial limb.*
- Design a zip up attachment and breathable liner.
- Implement composite fabric, alloy mesh and zip attachment material research.

Research and Design Development Objectives

- Identify transtibial amputee's aesthetic ideals regarding their artificial limb via a qualitative questionnaire.
- Design and develop an exo-skeletal transtibial artificial limb based on natural human form using composite fabric, alloy mesh lamination.
- Incorporate an *'Applied Human Aesthetic'* design methodology.

Project Goals

The Project Goals are to create a transtibial artificial limb that:

- is exo-skeletal in design replicating natural form;
- co-exists with current robotic developments;
- replicates natural kinetic return during walking phase;
- incorporates zip up attachment system with *breathable liner.*

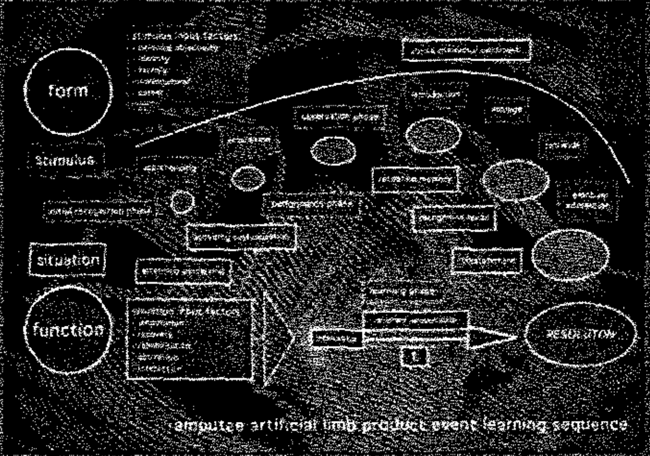

Table 1: Amputee artificial limb product event learning sequence. Buxton, D. 2005.

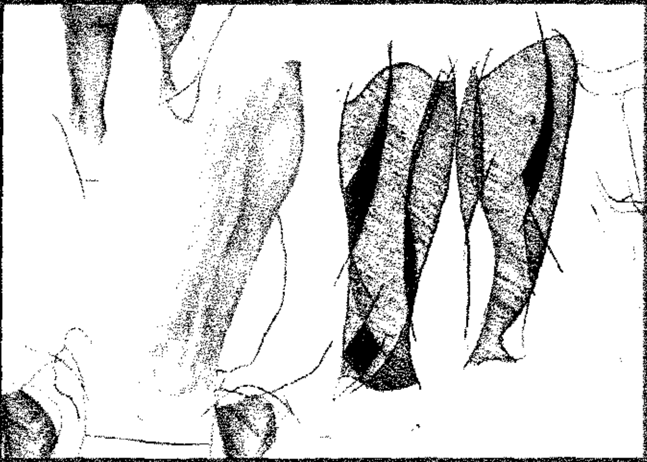

Figure 1: Myographic study of tibia area. Buxton, D. 2005.
Figure 2: Exo-skeletal tibia sectioned design blueprint. Buxton, D. 2005.

Initial Conclusions and Recommendations

- The application of an 'AHA' methodology as an artificial limb product design point of departure.
- Inclusion of industrial design practice during research and development.
- Greater involvement of amputees during design development process.
- Inclusion of amputee comfort factors.

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International Society of Prosthetics and Orthotics. Innovations for Quality Living. Poster Presentation: Hong Kong 2004.

Recipient of the 2005 Wellington City Council Creativity and Innovation Scholarship.

Invitation to present, "Pros-TH-otics" 2006. Wellington, New Zealand.

New Zealand Artificial Limb Board and ISPO New Zealand.

NZ Patent Pending.

Te Kunenga
ki Purehuroa

appendix b

Transtibial Amputee Questionnaire Results and Data Sheet

applied human aesthetic in artificial limb design research design development study

masters industrial design

development study