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**PRODUCT DEVELOPMENT  
OF EQUIPMENT FOR  
PEOPLE WITH DISABILITIES**

**The Development of an  
Axilla Crutch - A Case Study**

**A thesis presented in partial fulfilment of  
the requirements for the degree of Master  
of Technology in Product Development at  
Massey University**

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## ABSTRACT

The application of product development in the area of designing equipment for people with disabilities was studied using, as a case study, the development of a new design of axilla crutch.

From the literature available it became apparent that very little work on the product development process has been carried out within this industry. This situation exists side by side with, and may be strongly related to, a dearth of basic information on the market requirements and size for the equipment currently being used.

To overcome this problem for the case study a questionnaire was used to provide basic information for the axilla crutch. This was supplemented by a literature search which provided some information as to the essential operation of the equipment. This information provided the basis for the design of the new axilla crutch which was then field trialled.

From the results of the work carried out, it can be seen that the product development process in the disability sector is essentially the same as in other areas. The difference comes in the emphasis that needs to be applied to the initial market research and functional definition of the equipment, and the final assessment of the prototype.

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# 1.

## INTRODUCTION

Over the past decade, an increasing number and range of products are being made available to people with disabilities through the Health, Social Welfare, Accident Compensation Corporation systems. More recently, more products have been marketed directly to the consumer through the retail system. Surprisingly, there has been very little published information on the 'Product Development Processes' for this industry, one which is becoming a growth industry.

The product development process is widely used in the development of consumer goods (Earle and Anderson, 1985) and could also be suitable for the design of equipment for people with disabilities.

This thesis looks at the product development process and how it relates to design in the disability sector, using the design of an axilla crutch as a case study.

### 1.1. Products

Products are continually introduced into the marketplace e.g. household appliances, cars, and computers. Generally these fall into one of three categories:

- New models.

These are either this year's model of last year's product from the same company, or another company copying a good product to break into the marketplace. In many cases the changes are largely cosmetic or simple product changes to differentiate this year's from last year's product.

- New designs.

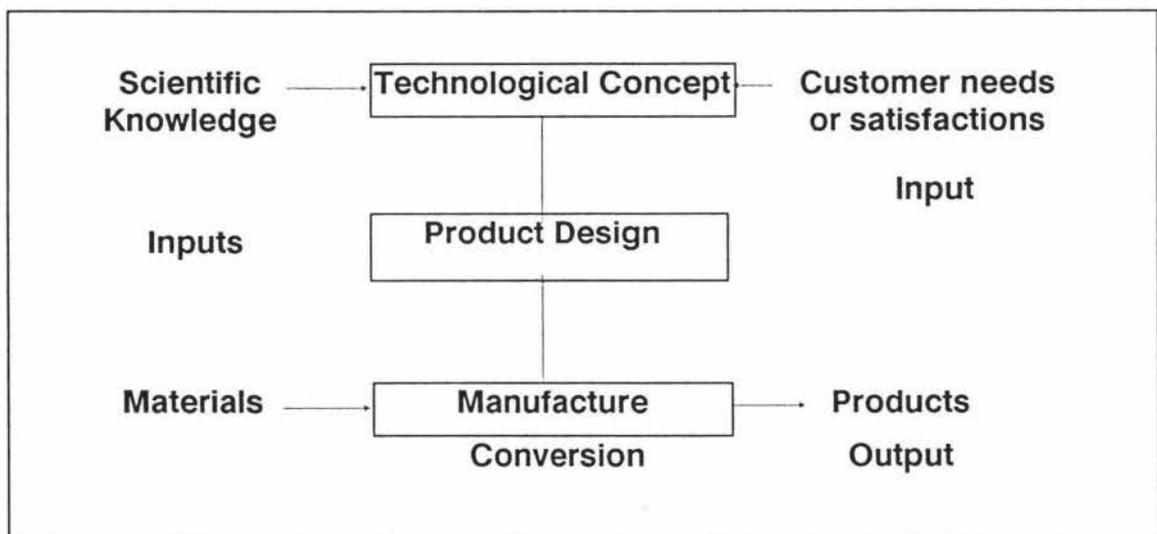
These are products which fulfill a need which is already being met, but in a new or innovative way. This may include radical new technology or materials, or a totally new mechanism for meeting the requirements of the market.

- New products.

These are totally new products to the marketplace. They are far less common than new models or designs. It is much more risky to develop products in this category as there is, by definition, no real measure of the market size, and in many cases no firm definition of the market need.

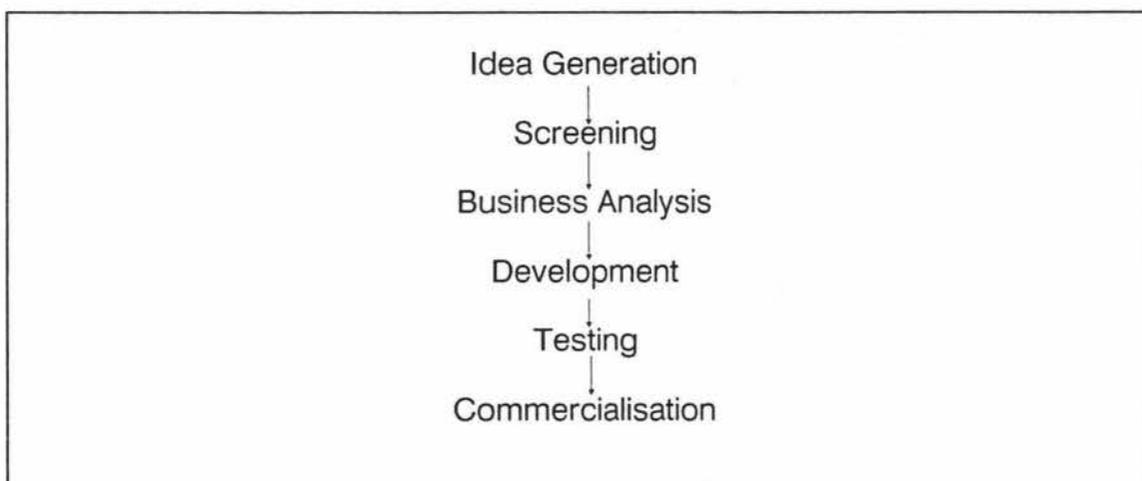
## 1.2. The Product Development Process

The process by which an idea is turned into a completed, marketable item is called Product Development. Product Development takes a number of inputs, such as consumer needs, available materials and scientific knowledge, and through a conversion process produces a final product as shown in Figure 1 (Twiss, 1980).



**Figure 1. Product Development (Twiss)**

The basic stages of this process are well defined and apply to all types of Product Development (see Figure 2). The differences are in the amount of emphasis placed on each stage. For example, if the product is a variation on an existing one there will probably be minimal emphasis on market research. On the other hand, if it is a new product a considerable emphasis will be placed on market research.



**Figure 2. Product Development Process (Hisrich & Peters)**

### **1.3. Variation for the Disability Sector**

When designing equipment for the disability sector, there is no major deviation from the normal product development process nor the use of Product Development techniques, but because of the nature of the device more emphasis needs to be placed on determining the consumer needs and testing of the product by the consumer.

Products developed for the disability sector generally come under the heading of 'Assistive Devices'. A definition of an assistive device is: 'a non-biological system, either external or internal, designed to replace or facilitate a human body function which has been lost or is deficient' (Rabischong (Ed), 1972). The equipment becomes part of the consumer's persona and, generally, is not changeable in the sense that we wear one set of clothes for work and another for leisure. In many cases the equipment is expensive and not purchased by the consumer but issued by an institution such as a hospital. This often means that the consumer does not have access to a replacement, an alternative product or additional items. Products in this area can range from highly specialised and customised 'one-offs', such as specialised seating systems, to a generally available common denominator solution, such as a wheelchair, which meets the needs of many consumers.

There are a number of products in general use by the population as a whole for which an individual does not have ready access to a replacement in case of failure, such as a fridge or stove. These items are essentially 'one off' by virtue of their cost. The difference between this type of product and the 'one off' used by a person with disabilities is that it has not been designed specifically for the individual and hence access to a similar device can suffice for the duration of repair, whereas the equipment used by the disabled person can be so customised that there is effectively no similar device available.

Products in the disability sector tend to operate in a highly interactive mode with the consumer. In many cases there is a physical interface between the product and the consumer. This can be a permanent interface as in the case of prosthetic devices or pacemakers; or one that takes significant loading from the consumer as in mobility equipment; or requires a high level of interaction as in the case of communication equipment. There are a large number of products in the marketplace which have this level of interaction such as typewriters, push bikes or even cars, but it is rare in any area, other than the disability sector, that it is accompanied by such a high level of dependence.

There are three significant factors, namely:

- Lack of alternatives
- High level of interaction
- High level of dependence

that make equipment for disabled people different from general consumer products. The main difference that this has on the Product Development Process is to require a greater emphasis on the definition of the consumer needs and an accompanying emphasis on the evaluation phase to ensure the consumer needs have been met.

It is also important, when bringing a new product to the market place, to be aware of the environment into which the product is to be introduced. In the disability sector this is very important and includes both the physical environments and the funding environments.

The physical environment may vary from rough roads to the interiors of institutions. The product may be faced with operating indoors or in wet conditions. It is important that all these extremes are considered in the design.

The funding of products in this area can be considerably different to the general products. Instead of the consumer directly purchasing the item, it may be bought by the representative of one organisation and then issued to the consumer through another department or even another organisation. In some cases the purchasing organisation may provide the full costs, in other cases only partial funding. This third party purchase can also have considerable ramifications on the service policy offered on the equipment.

#### **1.4. Historical Perspective on Equipment for People with Disabilities**

Prior to the Social Security Act of 1938 there was no provision for state paid medical or hospital services such as Occupational Therapy in New Zealand. Arrangements with voluntary organisations and friendly societies did exist to provide assistance for their members. The Act passed in 1938 referred only to the services, however, and did not cover any equipment needed by the patient. Changes to the system continued and equipment did come under the umbrella of a hospital service (generally the Out-Patient service) with the following equipment being supplied:

Contact lenses . . . . .	June 1947 . .
Hearing Aids . . . . .	November 1947 . .
Artificial Limbs . . . . .	April 1948 . .
Surgical Footwear . . . . .	December 1951 . .
Ileostomy and Colostomy Bags . . . . .	May 1955 . .
Plastic Protective Clothing . . . . .	May 1969 . .

Mist Tents and Similar Nebulisers . . . . . May 1969 . . .

(ref. Division of Hospitals, Hospital;Administration 1987)

This has been followed by further changes in policy, one of the more important being the provision of wheelchairs in 1973. Other major changes in the social system have been the Disabled Persons Community Welfare Act of 1975 which provides for wide ranging financial assistance for equipment for people with disabilities.

This change in policy and the resultant provision of equipment by agencies such as Hospital Boards has changed the type of market for equipment. Prior to 1973 with wheelchairs being purchased privately, there was a very uncertain market. The wheelchairs available were copies of overseas models, generally a very standard adult chair. With the provision of wheelchairs now being made through agencies such as Hospital Boards, the market has become a lot more certain and this has resulted in more variation of equipment as the manufacturers are now in a position where they can perform some research and development.

Now, instead of the consumer approaching a manufacturer or supplier to purchase the equipment, an agency will purchase the equipment on behalf of the consumer. The consumer then approaches the agency and the equipment is issued. As the consumer does not pay for the equipment, the purchasing agency has taken responsibility for the selection with a minimum of consumer input. Often the agency is so large that the purchasing section is not closely involved with the issuing section which further removes the consumer from input to the selection process. The result of this has been to make cost a more critical factor, with consumer requirements taking a lower priority. This situation has been further compounded by the lack of accepted standards for equipment in this area.

Out of this environment came a concern that more control over the quality of equipment in this area was needed. In 1980 the New Zealand Disabilities Resource Centre, in conjunction with the Hospital Boards Association and the Accident Compensation Corporation approached the Standards Association of New Zealand to prepare national performance standards for this equipment.

This has resulted in a programme of standards for:

- Manually Operated Wheelchairs
- Walking Aids for the Disabled
- Driving Controls for People with Disabilities
- Powered Wheelchairs
- Ward/Geriatric Seating.

There are two main approaches to the preparation of a Standard. The easiest approach is the Technical Standard. This type of Standard specifies the requirements of the equipment in physical terms, and the main result of this type of Standard is a uniformity of equipment. The second approach to Standards writing is the Performance Standard. In this type of Standard the function of the equipment is defined and tests developed to ensure these functions. No control over the manufacturing design or method is exerted. In the area of equipment for people with disabilities, the performance approach is the only effective approach as the user group has a very high level of interaction with the equipment. This, combined with the fact that there is no uniformity of physical characteristics within the user group, means that any Standard which results in uniformity in equipment design will in turn force manufacturers to produce equipment that does not meet the market need. This can be seen by the Standard for wheelchairs produced by the Department of Health and Social Security in England. Their Standard is essentially a purchasing specification to ensure interchangeability between parts from different manufacturers. In their Standard they specify two sizes of wheelchairs along with their physical dimensions. Evidence of this is shown by articles such as 'Have wheels, can't travel' by Alan Pipes, 1987 where he says "Disabled people are being further handicapped by badly designed and inappropriate wheelchairs, according to a recent report, which lays the blame at the door of the DHSS".

It was a result of the identification of the importance of performance that the New Zealand Standards in this area have been written as Performance Standards.

The process of defining the function of the equipment for the preparation of a performance Standard provides one of the first stages of product development, i.e. the definition of market requirements. It was decided to use a standard as a basis for research into the Product Development Process for the design of equipment for people with disabilities. The Author has been involved in the production of a set of performance standards for Walking Aids, which are now published, see NZS 5831:1989 Parts 1-3. It was decided to use this standard as a case study for the use of Standards in the product development process.

### **1.5. Aims of the Project**

This thesis followed the development of an item of equipment for use by people with disabilities to study the techniques and processes needed to develop equipment within this environment and to highlight the areas of difficulty.

The axilla crutch was selected as the item of equipment to form the basis of the case study. From research performed for developing a National Standard for walking aids, the need for equipment in specific areas, such as for people over 1.8m tall, was identified. This combined with the availability of a variety of technologies such as reinforced plastics led to the decision to use the design of an axilla crutch as an example of product development in this area.

There were several other considerations which made the axilla crutch a suitable topic for study. These were:

- The axilla crutch has been in existence for approximately 4000 years, but there are still problems with the equipment on the market (e.g. ease of adjustment).
- In preparation for the development of the National Standard for this equipment, considerable background work was carried out to gather information on the existing equipment.
- As the National Standard is nearing completion, information on the requirements for the crutch to comply with the National Standard are known.

- This type of equipment is used by both long term and short term users.

It was the aim of this thesis to investigate the product development process in the disability sector and to develop techniques for using consumer input in the preparation of design specifications and in the evaluation of the final product. The product developed, the axilla crutch, must be attractive, functional and safe.

## 2.

### **BACKGROUND ON PRODUCT DEVELOPMENT**

This chapter studies the product development process and discusses how it can be used in designing equipment for people with disabilities. It culminates with a proposed plan for the development of the axilla crutch.

#### **2.1. The History of Product Development**

The current age is one of technology. The technological changes seen over the last two centuries make those of the previous millennium shrink by comparison. Despite the criticism that technology comes under for negative effects, there is no disputing the positive lifestyle changes that have occurred.

Many products have come into existence as the result of the combination of several apparently unrelated events which are brought together by one individual. The development of the bicycle is an example of this as without the previous development of the pneumatic tyre, gas welding and the link chain, the construction of the bicycle would have been impossible. These events on their own, however, did not lead to the design of the bicycle, but it was the availability of these combined with the ideas of an individual that did. This type of 'product development' continued until post World War I.

America had an excess manufacturing capacity which had been developed for the war effort, and to utilise this capacity a more methodical approach to developing new products was taken.

This marked a change from an environment where the manufacturer could dictate to the marketplace creating situations such as with the Model T Ford 'Any customer can have a car painted any color they want, so long as it is black' (Garraty and James, 1974).

Manufacturing technologies were still used by manufacturers and designers in a relatively isolated way. Ideas for products were generated in-house or from research and development and then processed through to the market place. The main feedback as to the success of the product was the profit figure. The success of a product relied very heavily either on the ability of the designer to make exceptionally good judgments of what was required or the strong need of the market place for the product linked with very little competition.

The 1950's was a period of change for this type of environment. In the post war Europe there was such a lack of consumer goods that **anything** could be sold. In America a change of attitude came about as the consumer gained more power. This resulted in the need for designers and manufacturers to pay considerably more attention to the needs of the consumer. As the shortages of Europe eased this attitude became more prevalent in that corner of the world. With this change more and more structure was applied to the process by which an idea is promulgated through to a product.

There was, however, no automatic success for applying the techniques developed. Success rates of the the order of 10% were still the norm in 1980, although there is evidence to show that many of the failures could have been avoided (Twiss, 1980). Although a much more structured approach is being applied to developing new products, the indication is that the success rate has not changed much since 1968 (Rodocanachi et al., 1983).

A considerable amount of study has been carried out into both successful and failed designs to determine what the factors affecting the success of a product may be. The most critical of these are:

- A market orientation
- Relevance to the organisation's corporate objectives
- An effective project selection and evaluation system
- Effective project management and control
- A source of creative ideas

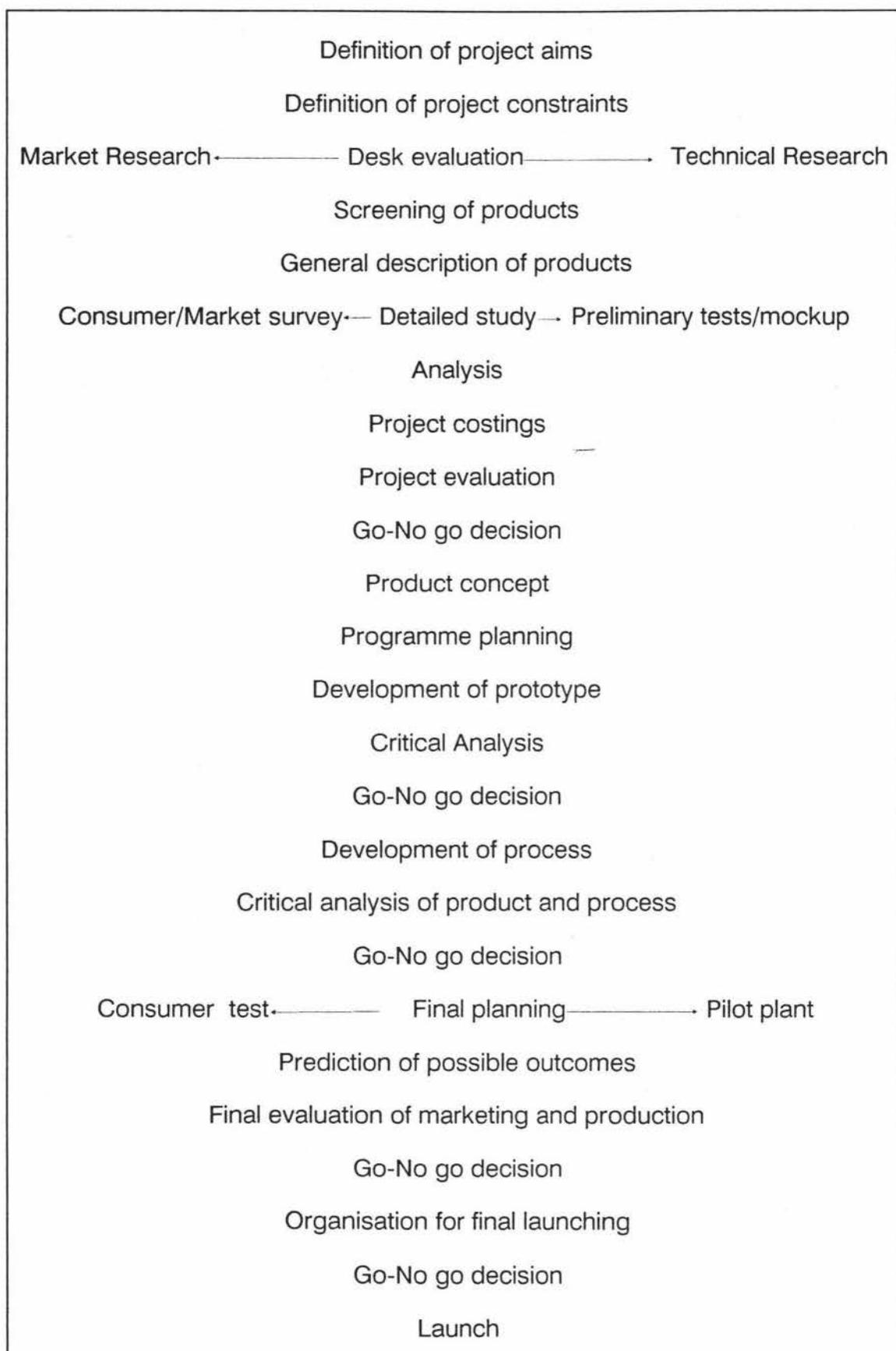
- An organisation receptive to innovation
- Commitment by one or a few individuals

(Twiss, 1980).

To maximise the probability of success, it is important that these factors are present in the development process. To ensure this, a structured approach should be applied to the development of a product. That is, a number of stages are progressed through, some repeated several times. There are different approaches put forward in different areas but the basic structure is generally similar with Figures 2, 3 and 4 showing differing levels of detail.



**Figure 3. Product Development Process (Rabischong, 1972)**



**Figure 4. Product Development Process (Earle, 1985)**

It is important that an organisational structure is implemented that will support this process. These stages in association with the critical factors mentioned earlier also imply the need for a project system, with a leader to ensure that the project succeeds, and an open communication environment between all areas concerned. The communication aspect is essential for a project to succeed. Rabischong, 1972 determined in a survey that of all the barriers present between Marketing and R & D, lack of communication was the major one representing approximately 31%.

## **2.2. Product Development in the Disability Sector**

When this process is applied to designing for the disability sector, no change is necessary to the actual process. The high level of interaction between the consumer and the product, however, implies that there will need to be a strong emphasis on the establishment of the consumer needs and the evaluation stages. It is imperative that a very specific and accurate definition of what the product must do is determined. This may be a difficult process as the equipment is often used by both prescribers and end users, two groups that will probably have differing requirements some of which may be conflicting; or by the user and an attendant or care giver at the same time such as is often the case with wheelchairs. This highlights the need to involve the consumers (prescribers, care givers and end users) in various stages of the product's development, specifically the market research and the evaluation stages.

As a result of the inherent difficulties in gaining an accurate picture of the consumer requirements, it is important that the design is thoroughly evaluated to ensure that it is correct. This evaluation has two aspects.

- Mechanical evaluation
  
- Human factors evaluation

The mechanical evaluation ensures the physical integrity of the design. It tests for strength and operation of the equipment. The human factors evaluation makes sure that the product is usable. What may be a perfect engineering solution to a problem may be totally inappropriate to the consumer for a number of reasons. The evaluation phase is crucial to getting the 'right' product to the market.

It can be seen from the above discussion that it is critical that market research is carried out to ensure that the requirements of all the consumer groups of the equipment are determined and used in the preparation of the design brief.

### 2.3. Product Development Plan for the axilla crutch

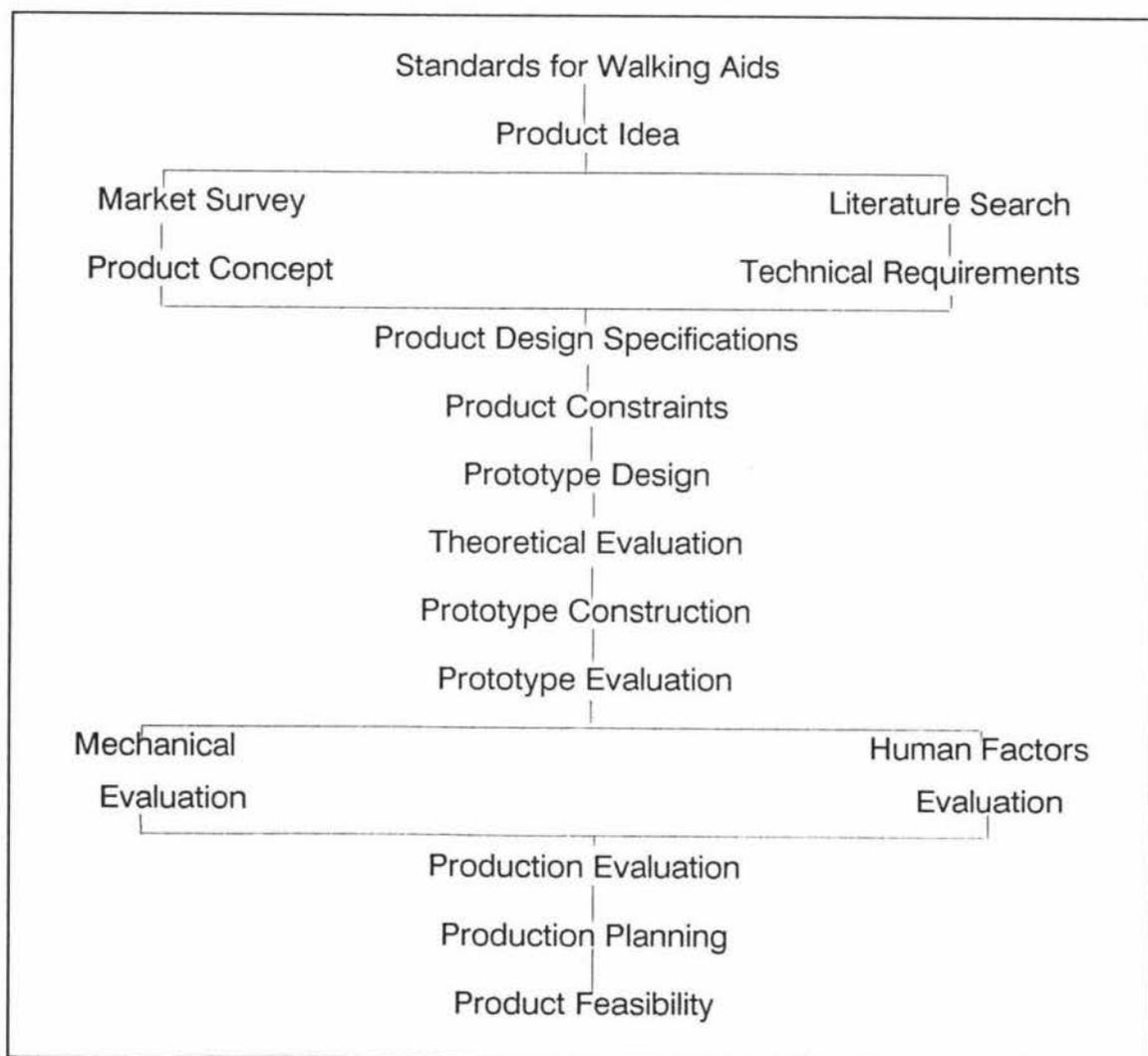


Figure 5. Axilla Crutch Development Process

The basic procedure used for the development of the axilla crutch is shown in Figure 5. For the purpose of this thesis the product development process was only taken from the Product Ideas stage to the Product Testing stage. The crutch was only developed to the point of a proven prototype.

### 3.

## **THE PRELIMINARY CONSUMER STUDY FOR THE AXILLA CRUTCH**

This chapter looks at the market information collection which formed the basis of the design of the axilla crutch. A considerable amount of consumer information had already been collected for the preparation of the New Zealand Standard for Walking Aids. As a result of this information being available, a mail survey was used to collect specific information required for the design.

### **3.1. Product Idea**

As has been stated earlier, it was the Author's intention to design an axilla crutch as a Case Study to illustrate the Product Development Process in the disability sector.

The idea for using the axilla crutch was based on information obtained from the background work for a National Standard for this equipment. This information highlighted the fact that although the device is relatively simple and has been in existence for a long time, there are still problems in the design area.

### **3.2. Methods of Surveying the Market**

The first stage of developing a new product is to determine the requirements of the market.

There are two main sources of market information, secondary data and primary data (Churchill, 1976). Secondary data is that information which already exists having been gathered for purposes other than the research being undertaken whereas primary data is gathered specifically for the current research. There is often also literature relating to research in allied areas available. Primary Data is that information gathered by the researcher specifically for the project on hand.

### **3.2.1. Secondary Data, Advantages and Disadvantages**

There are two sources of secondary data, the primary source and the secondary source. The primary source refers to the research group which gathered the information originally. This source generally details the collection process and is usually more accurate and complete. The secondary source is a source which obtains information from the primary source. This will include a number of statistical handbooks which collect information from such things as trade figures. These sources tend to condense the data and just publish the results. There is very little information on the collection and analysis stages included, and little evidence of the accuracy.

The advantage of secondary data is that it requires a minimum of resources to locate and assimilate. The value and amount of this type of data is generally underestimated as although it will very rarely fulfill all the researcher's information needs it will typically:

- serve to better state the problem under investigation.
- suggest improved methods or data to provide a better solution to the information needs.
- serve as a source of comparative information by which the primary data can be better interpreted. (Churchill, 1976)

The main disadvantage of secondary data is that it is generally collected for other purposes and therefore does not generally meet the current needs completely. This can be due to a number of reasons such as units, age of publication or format. The previously collected data may use different geographical boundaries or age categories for example. The other area of concern with secondary data is the accuracy. As the researcher may not have any information of the way in which the data was collected or analysed, it can be very difficult to be sure of the accuracy (Churchill 1976).

### **3.2.2. Primary Data, Advantages and Disadvantages**

Primary data is that information gathered by the researcher specifically for the project in hand. This means that the data collected should exactly meet the information needs of the researcher. The most commonly collected primary information collected relates to socioeconomic situations, attitudes or opinions, awareness, intentions, motivation or behaviour (Churchill 1976). There are two basic ways of collecting this information; communication and observation. Communication means that the subjects are questioned either verbally or in writing, whereas observation means that information is gathered by watching or monitoring behaviour.

The disadvantage of Primary Data is that it is expensive and time consuming to collect.

#### **3.2.2.1. Observation**

Observation is something that occurs in everyday life. We all watch what people around us do, and make decisions based on what we observe. When used as a means of gathering information for things such as market research however, the observation is more systematic in its planning and recording. Observation as a method of gathering information can be expensive. It requires trained staff, and will often incur high travel costs to get the staff to the observation sites. There is also the hidden cost of paying for unproductive time while the observer waits for the required behaviour to occur. Observation can be either structured or unstructured, disguised or undisguised.

Structured observation is possible when the behaviour of interest is clearly defined and can be categorised. An example of this may be to study how many shoppers choose brand A as opposed to brand B at the supermarket. The benefits of this approach is a tendency to minimise observer bias and to provide data which is more easily analysed. The disadvantage is that there is less flexibility in the information gathered, the observer has no means of recording information on any interesting but unpredicted behaviour.

In unstructured observation the observer notes down relevant behaviour. This requires a better understanding of the information needed but provides room for observer bias. The main benefit is the richness of information that becomes available and the ability to compensate for unusual or unexpected behaviour. The information gathered, though, is difficult to analyse and quantify.

In undisguised observation the observer will be obvious to the people being observed. The reason for their presence may or may not be apparent as people may act differently when they know they are being watched. One of the benefits of open observation is that the observer may be able to gather further data by identifying themselves.

In disguised observation, the observers are disguised; they are less intrusive and unlikely to modify the behaviour they are observing by their presence. There is, however, an ethical question to be asked when subjects are observed without their knowing it.

#### **3.2.2.2. Communication**

Communication means that the subjects are questioned to obtain the information required. This questioning can range in form from a self-administered mailed-out questionnaire to a face-to-face interview where the interviewer records all the relevant information.

Communication methods of information gathering have advantages in that they are versatile, relatively fast and can be very cost effective.

Information gathered in a questionnaire can cover a wide range of topics, many of which could not be gathered through observation. There can, however, be difficulties with accuracy as there is often no way in which the information can be confirmed.

As there are many methods of questioning subjects there is also a range of costs and time frames. The face-to-face interview provides the opportunity for gathering the greatest amount of information but it also is the most costly method. The costs include not only the travel of the interviewer(s) but also the training. Obviously with this method the only way to speed up data collection is to put more interviewers into the field. Mailed-out questionnaires have the disadvantage that there is no control over the responses or any opportunity for the respondent to seek clarification on any of the questions. A mailed-out questionnaire also requires a reasonable education level in the respondent. The benefits are that it is relatively cheap to produce, and a much larger sample can be taken for a relatively small increase in cost. It is important, though, that a good letter of introduction goes with the questionnaire as this will be the only means that the respondent will have of knowing what the questionnaire is for or the credentials of the researcher.

As was the case for observation, the questionnaires can be structured or unstructured, disguised or undisguised.

The Structured-Undisguised Questionnaire is the most commonly used type of questionnaire. All questionnaires are identical which makes the analysis simpler. The questions themselves are simpler or have limited reply options which make them easier to answer. The disadvantage of them is that there is generally little leeway for the respondent if there is not an option which defines their desired response. This makes the careful design of the questionnaire critical. It is important that all possible reply options are available to the respondent to prevent a bias in the replies.

The Unstructured-Undisguised Questionnaire type of questionnaire is distinguished by the fact that the purpose of the questionnaire is clear, but many of the questions will be open ended. These types of questions will gain more information from the respondent but the analysis becomes much more difficult. This type of questionnaire will often be administered by an interviewer and it

provides opportunities for the interviewer to follow up leads in the questioning. This type of interview tends to take longer than a structured questionnaire. A variation of this type of in-depth interview is the focused group interview. For this a number of respondents would be gathered together and the opinions and answers of each respondent would also be processed by the group and have an influence on the overall group response.

The Unstructured-Disguised Questionnaire type of questionnaire is often used for what has become known as motivational research. In many cases a respondent will not give accurate information because they may not be able to or it may damage their ego or their real opinion may conflict with what they consider the peer group reaction to be. To overcome these problems an unstructured-disguised approach may be used. With this type of questionnaire the information is extracted by "round about" means so the respondent may not be aware of what information they are giving. Techniques for this include word association, story-telling and sentence completion. The key to effective use of these techniques is to get the respondent to react to the stimuli presented and not to think too deeply about it.

This approach shares the same disadvantages of all unstructured approaches. Because the respondents may not receive exactly the same stimuli and as there is a greater need for interviewer interpretation, standardisation is far more difficult. There is also a greater difficulty in coding and analysing the responses.

To gain the attitude gathering benefits of the disguised approach with the easier analysis of the structured approach, the Structured-Disguised Questionnaire can be used. This type of questionnaire will determine what respondents 'know' about specific topics rather than what their attitudes towards them are. The basis for this approach is that the more people know about a topic the stronger their attitude towards it is. The difficulty can be in determining whether their attitude is for or against. This type of questionnaire is the least used in Market Research.

### 3.3. Secondary Data Gathered on Walking Aids

The secondary data available was the results from a previous survey used to collect information for the preparation of a National Standard for Walking Aids (Challis, 1983). The primary data was collected by a mailed out survey to physiotherapists.

As part of the programme to develop National Standards for equipment used by people with disabilities, the New Zealand Disabilities Resource Centre instigated a research project on the equipment being considered. The following reports were prepared:

- A Survey of Commonly Used Walking Aids in New Zealand (Challis, 1983)
- A Study of New Zealand Manufactured Motor Vehicle Hand Controls (Marshall and Challis, 1986)
- A Study of Motorised Mobility Equipment in New Zealand (Cutler and Challis, 1988)

During the preparation of these reports it was found that very little information on the New Zealand equipment and its use was available. The result has been that the reports prepared for the Centre have become the definitive pieces of work in the area.

In 1982 there was a survey of walking aids used in New Zealand (Challis, 1983). This survey was performed to provide information for the development of a National Standard for this equipment. The main objectives of the study were to:

- Provide the basic information required for the formulation of a Standard for Walking Aids.
- Provide an annotated catalogue of walking aids for use by prescription officers.
- Provide information for Hospital Boards purchasing walking aids.

The work was funded by the Palmerston North Hospital Board and the New Zealand Disabilities Resource Centre. A physiotherapist was employed under contract to carry out the survey under the auspices of the New Zealand Disabilities Resource Centre. She designed a questionnaire to ascertain the characteristics and problems of walking aids currently in the market. The questionnaire was piloted at the Palmerston North Hospital and then administered by interview to prescribers, purchasers and manufacturers within 23 organisations throughout New Zealand. Further information was gained by physically measuring the equipment. By the use of the one-to-one approach, considerable detail was obtained on the problems with current equipment.

This was the first major research into equipment for disabled people within New Zealand.

The main conclusions reached from this study were:

- Many aids have a range of adjustment suitable to a relatively small range of 'average' individuals.
- Many axilla crutches and elbow crutches are very uncomfortable for the user.
- Many aids are difficult to adjust with ease.
- Many newer lightweight crutches are susceptible to breakage.
- Many Hospital Boards have a limited range of the different types of walking aids available.
- Many prescriptions for walking aids take a considerable time to fill; this is particularly true of imported aids.
- Many Hospital Boards have to make decisions based on the severely limited amount of information available. This can result in a less than appropriate selection balancing the need for versatility and ease of maintenance against the cost. As this equipment is often purchased in bulk and by tender, the factor of cost often plays a disproportionately important role. (Challis, 1983)

### **3.4. Primary Data Collection on axilla crutches**

Identification of the consumers of equipment for the disability sector tends to be more difficult than in most other areas as there are often more than one 'user group' closely involved with the equipment. Obviously the person with the disability is the major consumer of the equipment but there are also the needs of support people such as therapists and nurses. Access to information is made more difficult by the fact that often the disabled users are less mobile and less forthcoming than many other groups. This situation is changing with organisations such as the Disabled Persons Assembly (DPA) and the New Zealand Federation of Disability Information Centres in existence making it much easier to get user input into the research.

The other major groups, such as therapists and nurses, are readily accessed by virtue of their clearly identified work places and professional associations. It is important that these organisations are approached as their input is also extremely valuable.

#### **3.4.1. Survey Plan**

Most surveys go through the same stages or cycles of stages (see Figure 6), and this was used as the basis for the survey to collect the primary data needed for the design of the axilla crutch.

#### **3.4.2. Survey Method Selection for the Project**

The study was to determine the criteria for a new design of axilla crutch. The details sought were those relating to usage and problems with existing equipment. It was hoped through the survey to be able to determine the consumer needs and identify user needs which were not being met.

In view of the type of information required it was decided that a communication technique would be needed as observation would not provide information on areas where the users' needs were not being met, or necessarily give sufficient information on the problem areas.

- Deciding the aims of the study and the hypothesis to be investigated.
- Reviewing the relevant literature; discussions with informants and interested bodies.
- rch instruments.
- rch instruments.
- The sampling process; selection of the people to be approached.
- The field work stage; data collection and returns.
- Processing the data, and coding the responses.
- The statistical analysis (simple at first, but becoming more complex); testing for statistical significance.
- Assembling the results and testing the hypothesis.
- Writing up the results; relating the findings to other research; drawing conclusions and interpretations.

**Figure 6. Stages of a Survey**

Having decided on a survey, the type of survey was determined. The information to be gathered was basically factual, as opposed to attitudes or opinions. This meant that a disguised questionnaire would not be needed. To make the responses easier for the respondents, it was decided to use a very structured questionnaire. It was thought that this would be appropriate as the earlier survey provided considerable information, leaving this survey to answer specific questions. The decision to use a mailed-out questionnaire was based largely on economics and the ability of the questionnaire to reach a large sample of the population. Focus groups were not considered as this would still have involved high costs and considerably more time on the part of the respondents.

The survey was to provide the basic functional requirements for the new design of axilla crutch.

### **3.4.3. The Target Group**

To determine the requirements for the design of the axilla crutch it was necessary to survey the groups involved with the equipment. There were a number of basic groups involved;

- manufacturers
- purchasers
- prescribers
- users

An interview type survey was carried out in 1982 of the manufacturers, purchasers and prescribers (Challis, 1983). It became clear from the results of this work that it would be very difficult to reach the user groups directly as very little record keeping of the issue of the equipment is done. It was decided therefore, to approach the prescribers of the equipment, who are in contact with the user group, for information on the functional requirements. The physiotherapists are an easily defined group as each hospital has a Physiotherapy Department. This group is involved in training the users of this equipment in the correct methods of use. They also have some say in the ordering of the equipment.

### 3.4.4. Data Collection and Returns

A structured questionnaire was designed (see Appendix A) and was piloted at the Physiotherapy Department of the Palmerston North Hospital. The Department of Health was then approached for permission to canvas the physiotherapy departments of all of the hospitals within New Zealand. Upon receipt of permission the questionnaires were mailed out in March 1987 to the 93 physiotherapy departments in the hospitals throughout the country. This represents a 100% population sample. A period of two months was allowed for the return of the questionnaires. No follow up letters were sent to encourage late replies.

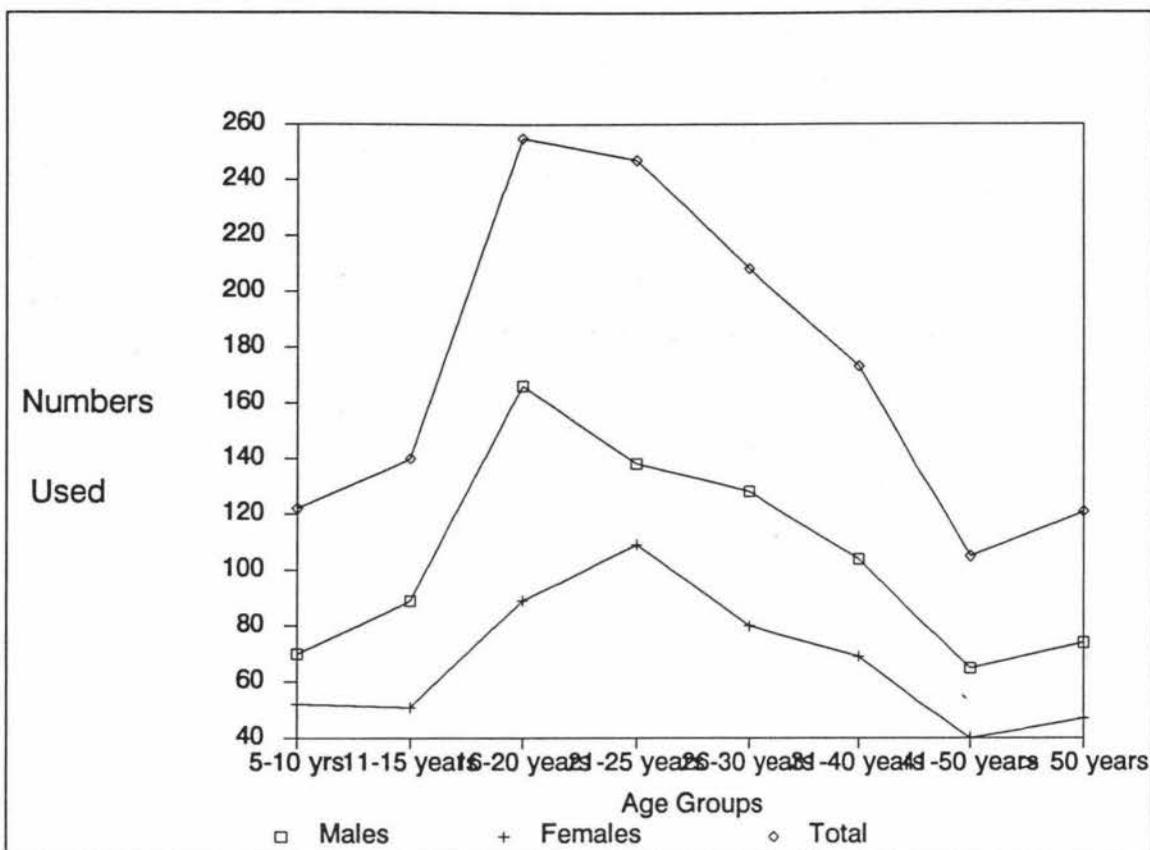
Of the 93 questionnaires sent, forty seven were returned which represents a 50% return rate. Of those returned eight were not applicable as the departments do not use crutches (such places as maternity hospitals).

### 3.4.5. Processing the Data

The evaluation that follows was therefore based on the return of 39 questionnaires. These responses represent a cross section of hospitals ranging from large hospitals such as Wellington Hospital through to smaller units, such as Opotiki and included specialist units such as the Wilson Home and Otara Spinal Unit.

Age	Male		Female		Total	
	No	%	No	%	No	%
5-10 years	70	8	52	10	122	9
11-15 years	89	11	51	9	140	10
16-20 years	166	20	89	17	255	18
21-25 years	138	17	109	20	247	18
26-30 years	128	15	80	15	208	15
31-40 years	104	12	69	13	173	13
41-50 years	65	8	40	7	105	8
Over 50 years	74	9	47	9	121	9
Total	834		537		1371	

**Table 1. Total Number of Crutches issued in 1986**



**Figure 7. Axilla Crutch Usage by Age and Sex**

All percentages quoted in the analysis of results are based on the 39 valid responses. Not all respondents replied to all questions and there was not necessarily any significance or consistency in the non-answered questions. Where figures do not total 100% or 39 replies this was due to non-responses. No statistical analysis was carried out.

### 3.4.6. Results of the Survey

#### 3.4.6.1. User Group

The total number of crutches issued, grouped by sex and age, is shown in Table 1. Not all respondents were able to supply this information, so the figures in the table are not indicative of the total usage in the country but they do provide information on the usage distribution.

See Figure 7 for a graphical representation of the usage.

It can be seen from the above figures that the main users of axilla crutches were males in the 16-30 year age group (32% of total usage).

### 3.4.6.2. Physical Characteristics of User Group

To determine if there was a gap in the size ranges of equipment currently being supplied, respondents were asked to state their opinion as to whether four basic user height ranges were not being adequately met. Table 2 details the responses received.

<b>Size Range Needs</b>	<b>No</b>	<b>Yes</b>
< 1.5m	24 (62%)	13 (33%)
1.5m-1.65m	3 (8%)	29 (75%)
1.66m-1.8m	2 (5%)	26 (67%)
> 1.8m	29 (75%)	8 (21%)

**Table 2. Size Needs for Crutches**

The two groups needing improved provision for crutches were the small and the large users. As the greatest number of users were young males, who were generally large, it appeared from the survey that the new design must consider their needs.

From the survey, users over 1.8m had the following weight characteristics:

**'Average'** weight

mean = 83kg

SD = 6.2kg

range = 72-95kg

**'Maximum'** weight

mean = 118kg

SD = 14kg

range 95-150kg

The problem areas in terms of the adjustment range are at the extremes, as would be expected, with a clearly identified need for users over 1.8m.

There was reasonably good agreement that the average weight of users over 1.8m would be approximately 83kg. The maximum weight was harder to define, possibly as it is harder to define the users who belong to the upper percentile weight groups. To provide a design to meet the requirements of the majority of the user group, and based on the mean 'Maximum' weight of 118kg, a design figure of 120kg was selected.

### 3.4.6.3. Use and Reasons for Use of Crutches

The major reason for using axilla crutches is to relieve weight bearing. In most cases this was following fractures or sprains of the legs. The next common cause was post surgery.

The average time that a patient used a pair of axilla crutches was:

mean = 6.2 weeks

SD = 3.8 weeks

range 1 - 16 weeks

It can be seen from this that there was a wide range of usage times of the crutches.

	% Axilla Piece used for Stability and/or Weightbearing			
	0%-24%	25%-49%	50%-74%	75%-100%
Stability	6 (15%)	4 (10%)	3 (8%)	20 (51%)
Weightbearing	13 (33%)	5 (13%)	3 (8%)	7 (18%)
Both	6 (15%)	6 (15%)	1 (3%)	4 (10%)

Information presented as number of respondents (% of sample)

**Table 3. Axilla Piece Usage**

The axilla piece of the crutch can be used for both stabilising the crutch in use and for weightbearing. The correct usage is purely for stability. Table 3 provides detail on how the axilla piece is used in the different ways.

The figures showing the usage of the axilla piece for weightbearing indicated a high misuse of the crutches.

#### 3.4.6.4. Design of Crutches

To assist in the definition of the design of the crutch, a number of questions were

	Yes	No		
Is it important that the crutch can be used in either hand?	37 (95%)	2 (5%)		
Is the existing axilla piece acceptable?	14 (36%)	21 (54%)		
Are existing crutches sturdy enough?	20 (51%)	11 (28%)		
What % of Users would require a sculptured handpiece?				
	0-25%	26-50%	51-75%	76-100%
	18 (46%)	4 (10%)	1 (3%)	6 (15%)
Are existing crutches generally:				
	Too light 1 (3%)	OK 35 (90%)	Too heavy 3 (8%)	

**Table 4. Design Considerations for the Axilla Crutch**

asked to determine the importance of different characteristics of the crutch (see Table 4). From Table 4 it can be seen that it is important that the crutches are able to be used in either hand. There was not a strong feeling about the design of the axilla piece but it would appear that it could be improved.

It can also be seen that there is considered to be little need for sculpturing the handpiece. This would correlate with the strongly expressed need for the crutches to be ambidextrous.

From the above results there is no strong dislike of the present levels of construction. Information on the common sites of failure showed the adjustment positions to be the major problem area.

### 3.4.6.5. General

To provide a background for the overall design, the respondents were asked to rate cost, weight, adjustment range and durability on a five point importance scale to determine the priority of some of the overall requirements (See Table 5).

It can be seen that while cost and weight were considered important, the major concerns were in the areas of adjustment range and durability.

Factor	Not			Very	
	Important			Important	
Cost	0 (0%)	1 (3%)	13 (33%)	8 (21%)	17 (44%)
Weight	0 (0%)	0 (0%)	13 (33%)	14 (36%)	12 (31%)
Adjustment Range	0 (0%)	0 (0%)	1 (3%)	4 (10%)	34 (87%)
Durability	0 (0%)	0 (0%)	1 (3%)	5 (13%)	33 (85%)

**Table 5. General Requirements for the Axilla Crutch**

There was a variety of comments made. The most common related to the need for easily adjustable crutches that are comfortable.

### 3.5. Product Concept

From the results of the survey the following product concept was developed:

- There was a need for crutches designed to suit the taller (1.8-2.0m) users.
- The crutches must be able to carry a 85-90kg user as a minimum with a design user capability of 120kg.
- Crutches must be able to be used in either hand.
- Crutches must be easily adjusted, with no weakening of the overall design.
- The axilla piece needs to be designed for comfort, perhaps with a removable padded cover.

## 4.

### PROTOTYPE DESIGN

The previous chapters detailed the overall process of collecting information on which to base a design, and the information gathered in this specific case.

This chapter looks at the design of an axilla crutch to fulfill the needs identified.

#### 4.1. Historical Use of Crutches

Crutches and canes have been used as rehabilitative devices for over 4000 years (Shoup et al. 1974). The basic design of crutches has changed very little over most of this time period. Essentially, it is a device which carries the user's weight through the hand and via a shaft to the ground. Another shaft from the handle goes up to a stabilising piece which is held between the upper arm and the chest wall. These devices have been used in makeshift forms as used by Long John in Robert Lewis Stevenson's book "Treasure Island".

The crutch is used to remove the need for load bearing by the legs. It can be used to assist ambulation by taking a portion of the weight or, through the use of a 'swing through' gait, it takes all the load bearing off the legs for portions of the ambulation cycle. An early reference in literature to the design of the axilla crutch is in the Medical Record in 1883 by James Taylor. From this time on there have been a number of publications detailing aspects of crutch usage and design (Shoup et al., 1974; Stallard et al., 1980; Shoup & Sanchez, 1980; Nava & Laura, 1985; Goh et al., 1986).

#### 4.2. Product Design Specification

The market research provided a functional description of the axilla crutch i.e. it had to be:

- Able to be used in either hand.
- Suit a user of over 1.8m.
- Suit a user weighing at least 95kg.
- Easily adjustable.

This gave the overall requirement for the device. From these basic definitions it was necessary to determine the actual dimensions needed, the strength required and a specific design. To determine these design specifics, further information was needed on existing designs, body dimensions, and materials.

### 4.3. Existing Designs

Almost all axilla crutches used in New Zealand are of the same basic design. There are two stems which come down from the axilla piece, support the handle and terminate on a shaft which goes to the ground (see Figure 8). To adjust this design it is necessary to remove the two bolts which fix the two stems to the shaft. By springing the two stems the handle can be moved, and by the position of the shaft when the device is reassembled, the overall height can be adjusted.

The current designs are constructed from either mild steel or aluminium.

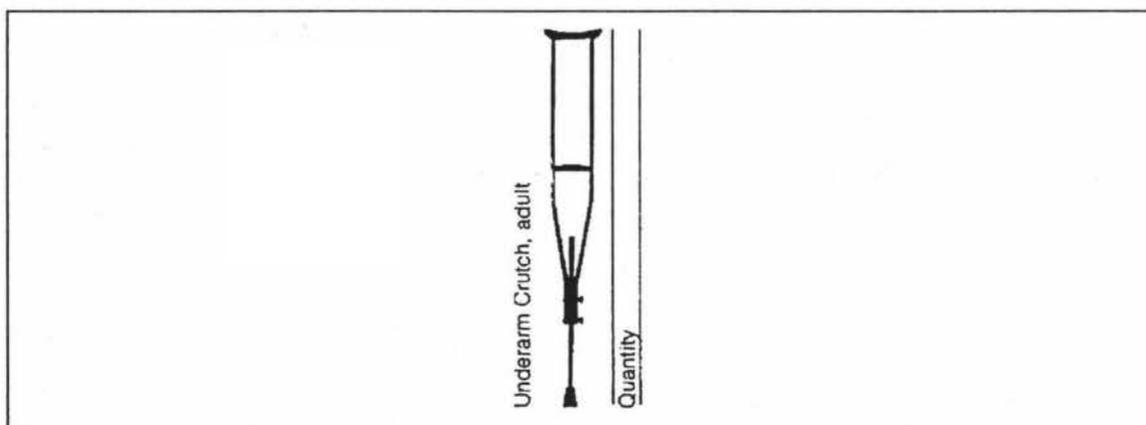
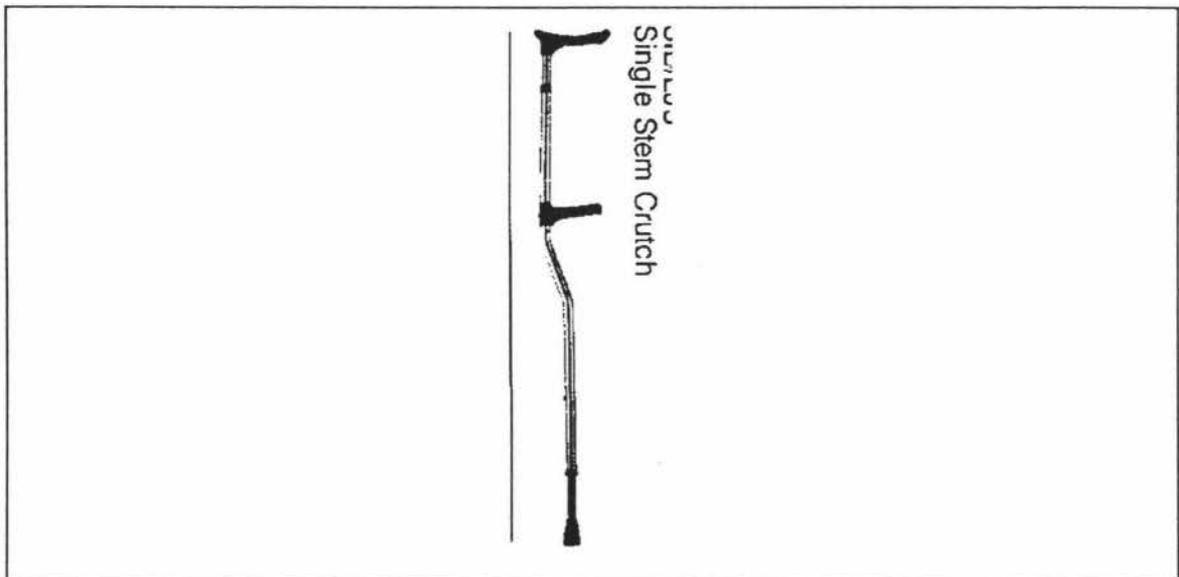


Figure 8. Existing Axilla Crutch Design

This basic design differs from the shape seen through history (i.e. the Long John Silver type) through the use of two stems. This design approach makes the device inherently stronger by taking the loading through the two stems and eliminating much of the bending moments on the axilla piece and handpiece. Unfortunately, almost all the existing designs have the stems terminating on an adjustment hole in the lower shaft. This results in a weakening of the overall design which is shown by the number of failures that occur at this point in comparison to other failure modes.

There has been one design of a single stem axilla crutch in the New Zealand market in recent years. It was constructed of aluminium and had telescoping shafts which curved below the handle to give a similar geometry to existing designs (see Figure 9).



**Figure 9. Single Stem Type Design on NZ Market**

The method of adjustment was by spring loaded buttons which protruded through holes in a telescoping section on the crutch. This method of adjustment was convenient, although after prolonged use, holes used for this type of adjustment elongate and the crutch tends to 'rattle'.

Unfortunately, the aluminium used was not strong enough to withstand the bending moments applied in use and the device was removed from the market.

#### **4.4. Literature Search**

The majority of the research performed on crutches has been in the area of the biomechanics of use. This research provides important information on the loading levels in different parts of the device under different usage conditions.

Stallard et al. (1980) from their research for 11 subjects obtained a range of loadings through the base of the crutch of 42-63% of body weight with an average of 51%. Goh et al. (1986) instrumented a conventional design of crutch with load cells in each of the side stems and the bottom shaft. This crutch was then used by 10 subjects and information on the loading levels at each instrumented point for both correct and incorrect use were recorded. Their work determined that for correct usage the load through the crutch tip was 49.3 - 54.4% of the users' body weight.

Based on this work it was assumed that 50% of the body weight will be taken through the crutch in normal usage. It was decided that the crutch would be designed with a safety factor of 2, i.e. the materials and design selection would be based on a loading of full body weight.

#### **4.5. Dimensions**

From the basic criteria of a user over 1.8m, several dimensions had to be determined. These were the height of the axilla piece and of the hand piece. The adjustment range also had to be determined to provide information on the lengths of sections of the crutch which provided for adjustment.

The Humanscale data sets by Diffrient et al. (1974) were used to determine the dimensions. The data sets detail the lengths of each limb segment, their weight and centre of gravity. This data is presented for a range of heights with information relating to the differences between male and female measurements. These sets relate to the North American population and were used primarily as there was no

equivalently detailed information available for the New Zealand population. Some population dimensions are available, such as the stature and body weight figures in a report by Birkbeck (1977). A simple comparison of the 97.5%ile mark showed an agreement between the New Zealand and American figures for height but the New Zealanders were heavier.

The Humanscale data was used to provide information on the standing height and the shoulder height. Using the figures for upper arm length, lower arm length and wrist to centre of grip distance, the distance from the ground to the centre of grip with the elbow in  $15^{\circ}$  of flexion was calculated (see Table 6).

<b>Standing Height (mm)</b>	<b>Shoulder Height (mm)</b>	<b>Grip Height (mm)</b>	<b>Weight (N)</b>
1677	1321	888	712
1701	1343	906	730
1726	1363	919	748
1752	1384	936	770
1779	1408	952	788
1803	1427	966	800
1829	1448	981	819
1855	1471	997	837
1881	1492	1015	854
1905	1511	1026	872
1930	1534	1041	890
1955	1554	1056	907
1981	1575	1071	925

**Table 6. Body Dimensions (Diffrient et al.)**

It was decided to design the crutch for a maximum user height of 1930mm (This is a height greater than the 99%ile). To determine height of the axilla piece, the shoulder height was taken. This value was higher than it should be, but it was considered better to err on the size of over adjustment. This height corresponds to a user weight of 90kg. As the New Zealand figures for weight appear to be higher than those for North America, the design user weight of 95kg allowed for this higher value. Based on approximate adjustment ranges available it was decided to design the crutch to suit a 1680mm user at the lowest adjustment.

Using these figures the following design criteria were determined:

	Maximum Adjustment for 1.93m tall User	Minimum Adjustment for 1.68m tall User
Distance from ground to Axilla Piece	1530mm	1320mm
Distance from ground to Handpiece	1040mm	890mm

**Table 7. Basic Dimensions of Crutch**

#### **4.6. Prototype Designs**

One requirement became very clear from the market research, that is the need for easy adjustment. To achieve this, it was decided to use a single stem design as opposed to the more conventional two stems meeting a single base piece.

The requirement for ease of adjustment indicated that the method of locking the adjustable section would be of prime importance. With a single stem design the method of a series of adjustment holes with a spring loaded locking pin is simple. This method was used by the Long John Silver design and in most designs of elbow crutches. The disadvantage with this method is that the drilling of holes weakens the materials, and with use the holes distort and the crutch has a tendency to 'rattle'.

To overcome the inherent weakness of the bent tube used in the Single Stem design, the first design used a hand piece which would provide for an axial loading of the lower stem, while providing for an offset upper stem (see Figure 10) to replicate the geometry of the conventional crutch design. This resulted in three sections in the design.

- The upper stem, which had to be adjustable and carry the axilla piece.
- The handpiece, which had to be strong enough to take the loading on it while also having mountings for the upper and lower stems.
- The lower stem, which had to be adjustable.

The design became quite complex where the stems were fitted to the handpiece.

The second design had a single telescoping section with the axilla piece offset at the top, and an adjustable handpiece (see Figure 11). A similar construction had been used by Nava and Laura in 1985. This approach required that the handpiece be attached to the stem such that it could be adjusted and locked into position. The design for a locking mechanism which would be simple to operate and not present any surfaces or edges which would impinge on the user proved to be difficult.

The final design used the same locking bung for both adjustments and had the upper stem and the lower stem sliding in a middle section which had the handpiece attached (see Figure 12).

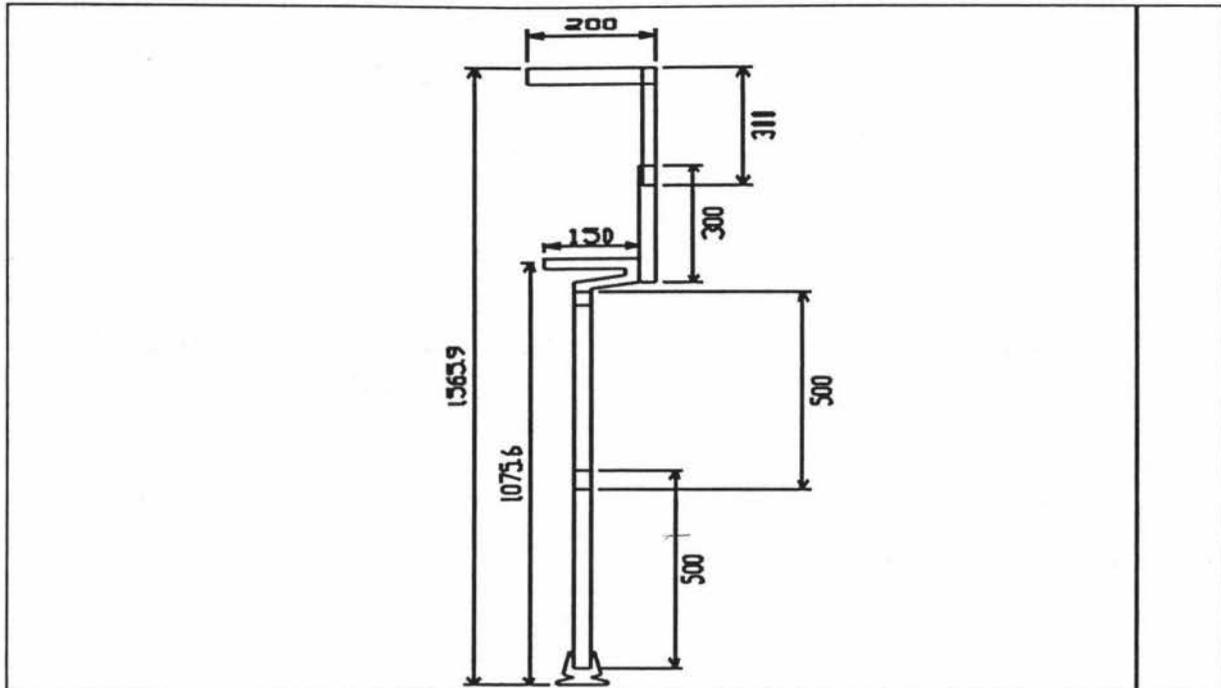


Figure 10. Axilla Crutch - Offset Stem design

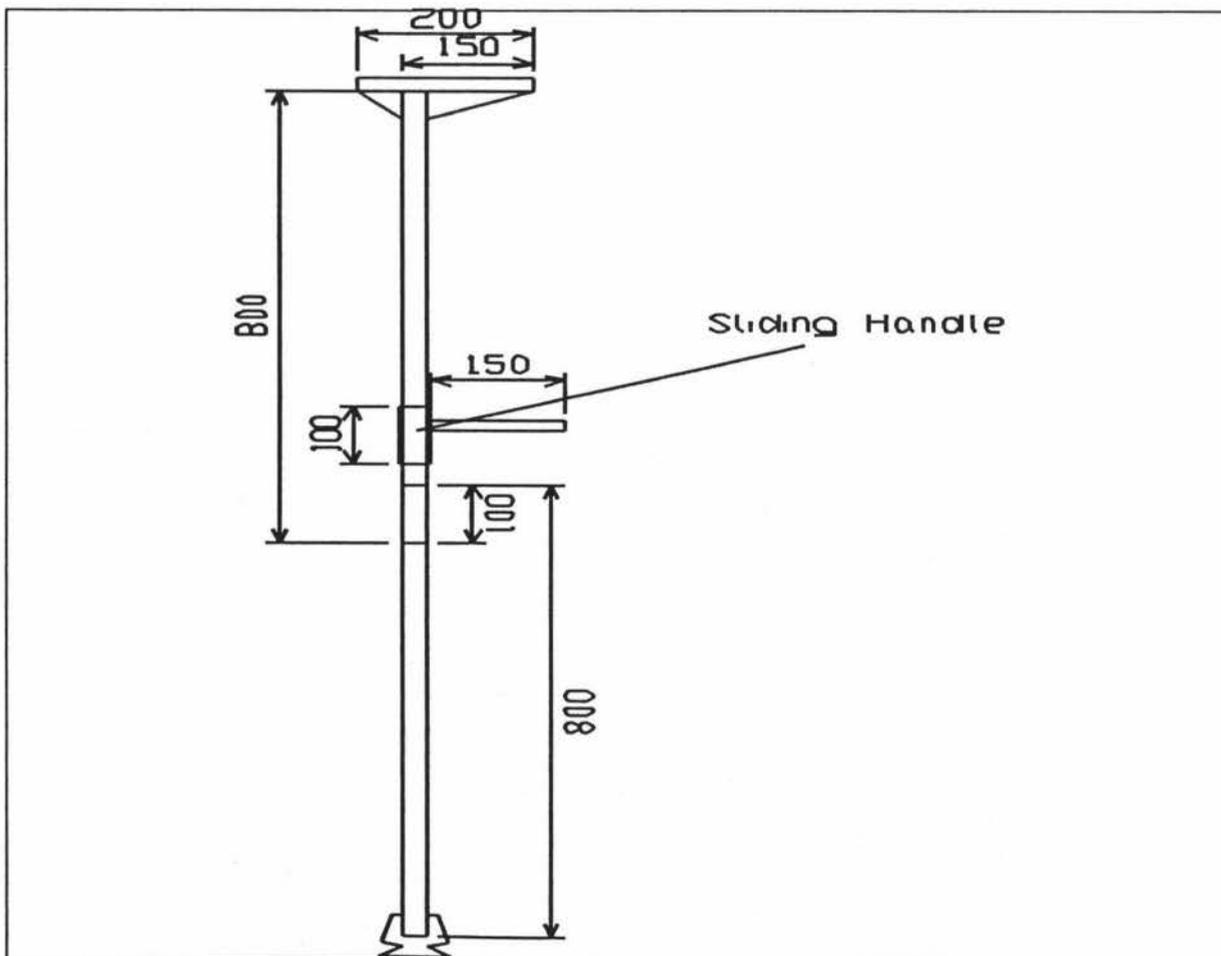
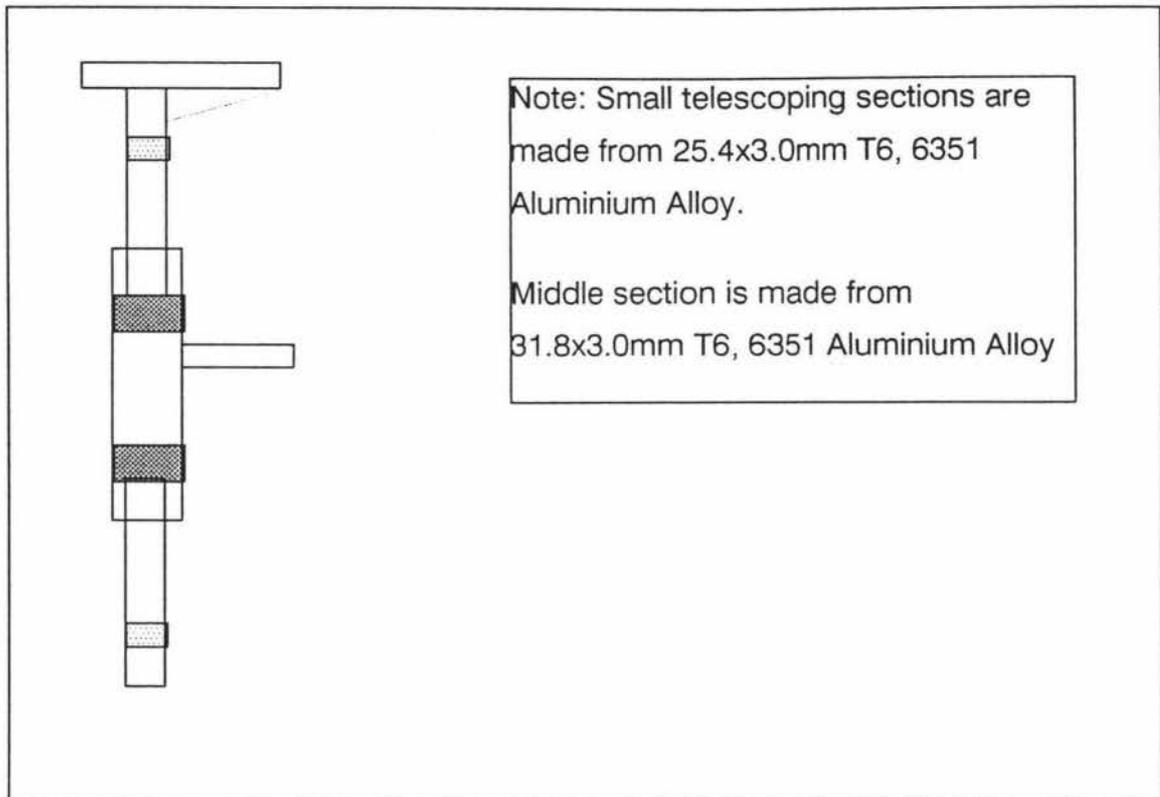


Figure 11. Axilla Crutch - Straight Design/Sliding Handle



**Figure 12. Axilla crutch - Fixed Mid-Section Design**

#### **4.7. Theoretical Evaluation**

The initial material of choice was a reinforced plastic. The problem with this material, however, was that information such as the yield stress were not available. To simplify the initial prototype design it was decided to use an aluminium alloy as the mechanical properties of these alloys were readily available.

To determine the suitability of the different alloys and the different tubes available, a stress calculation was performed. Certain assumptions were made:

- The telescoping tubes could be considered as a homogenous unit.
- The worst case loading was full body weight applied to the axilla piece.
- The loading would be applied roughly to the centre of the axilla piece.

Based on these assumptions the stress levels for different tube dimensions were calculated. These stress levels were then compared to the yield stress levels for different alloys. Table 8 shows the results of the calculations. The different alloys are listed at the bottom of the table, a '+' means that the tube dimensions of that alloy would be acceptable for the design, a '-' means that it is not.

Stress Calculations														
Load	931.95	931.95	931.95	931.95	931.95	931.95	932	932	932	932	932	932	932	932
Offset	75	75	75	75	75	75	75	75	75	75	75	75	75	75
O.D.	19.10	19.10	22.20	22.20	25.40	25.40	25.00	25.40	28.60	31.70	31.70	34.90	38.10	38.10
Wall	1.22	1.42	1.42	1.22	1.22	1.42	2.00	3.18	1.42	1.42	1.63	1.42	1.42	3.18
Thickness														
Stress	243	216	155	175	131	115	91	64	89	71	63	58	48	25
I.D.	16.66	16.26	19.36	19.76	22.96	22.56	21.00	19.04	25.76	28.86	28.44	32.06	35.26	31.74
6061-T4	-	-	-	-	-	-	+	+	+	+	+	+	+	+
6061-T6	-	+	+	+	+	+	+	+	+	+	+	+	+	+
6063-T4	-	-	-	-	-	-	-	+	-	-	+	+	+	+
6063-T5	-	-	-	-	-	-	+	+	+	+	+	+	+	+
6063-T6	-	-	+	-	+	+	+	+	+	+	+	+	+	+
6351-T4	-	-	-	-	-	-	+	+	+	+	+	+	+	+
6361-T5	-	+	+	+	+	+	+	+	+	+	+	+	+	+
6361-T6	+	+	+	+	+	+	+	+	+	+	+	+	+	+

**Table 8. Stress Calculations for Standard Tubes**

There were several tubes which would meet the requirements for the design. To provide the telescoping function, two tubes are required such that the internal diameter of one is only slightly greater than the outside diameter of the other. Based on this, and information on available stocks, the 25.4 x 3.0mm T6 6351 and the 31.8 x 3.0mm T6 6351 tubing were selected for the construction of the prototype.

## 4.8. Locking Bung Design

A number of designs of locking mechanisms were studied (see Figure 13). Option 1 was the basic design finally selected, so I will discuss this later.

**Option 2** consisted of slotting the internal tube and having a tapered plug which would be drawn into the inner tube forcing it to spread out and create a friction lock with the outer tube.

**Option 3** had the outer tube tapered and threaded. A 'nut' with a matching taper and thread would then be tightened up on the outer tube causing it to compress onto the inner tube.

**Option 4** had the outer tube slotted with raised, tapered pieces on each side of the slot. A handle with a matching taper fitted over the raised units, and the tapered surfaces interacted such that when the handle was rotated down, the tapers would force the slot to close, compressing the outer tube onto the inner tube.

**Option 5** had a band around the outer tube, and a threaded stud attached to the band and pressing against the outer tube. When the stud was screwed in it would tension the band and compress the outer tube against the inner tube.

Several of these involved slotting the larger tube in the telescoping section to enable it to be compressed on the smaller. This was not considered suitable as it would weaken the materials used. Some of the other solutions resulted in parts of the lock projecting out from the crutch. This was considered unacceptable as it could cause injury through the user grazing themselves on it.

**Option 1** had a rubber bung which was compressed between two washers. This assembly was attached to the inner tube. When the bung was compressed it provided a friction lock against the inside of the outer tube. The solution provided the benefits of not having to weaken the materials and a distributed loading when used was the compressible rubber bung (see Figure 14). It was selected for prototyping. It is relatively easy to manufacture and provides for continual adjustment over the adjustment range.

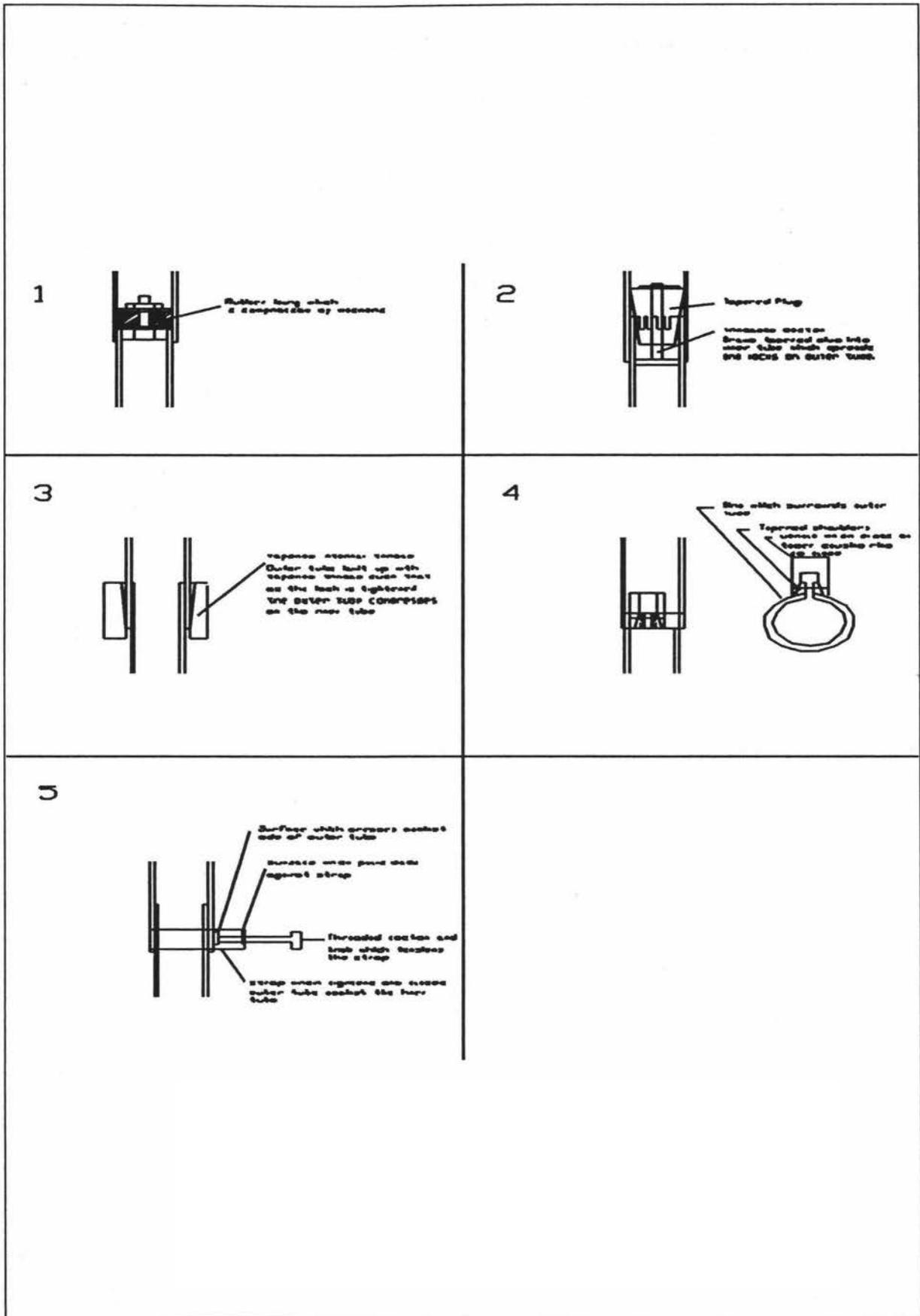
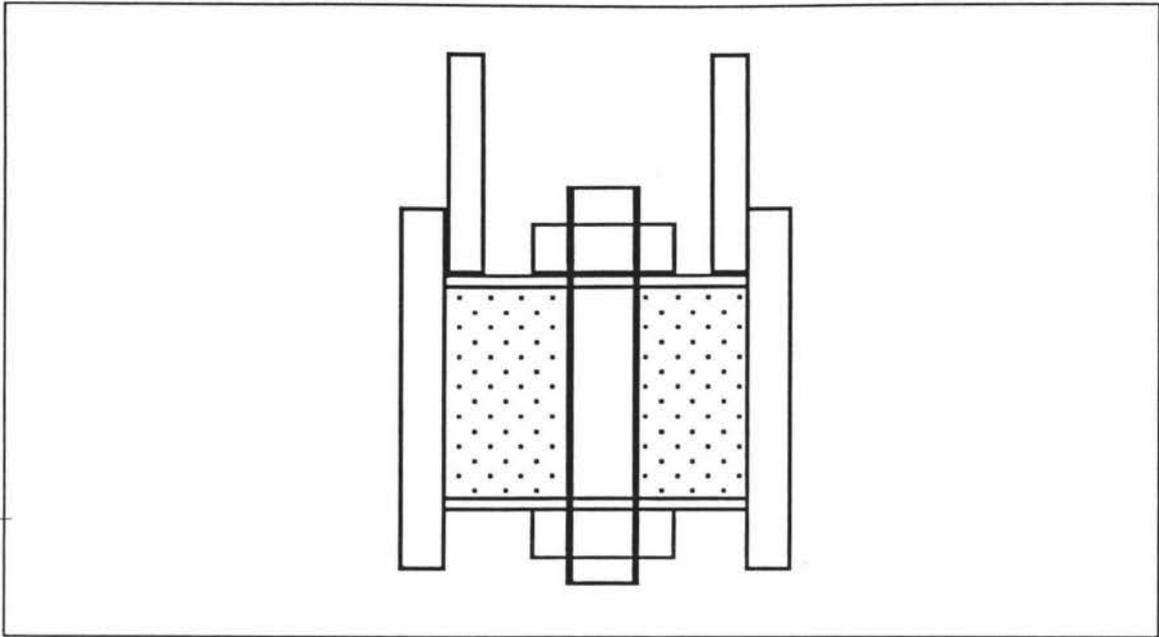


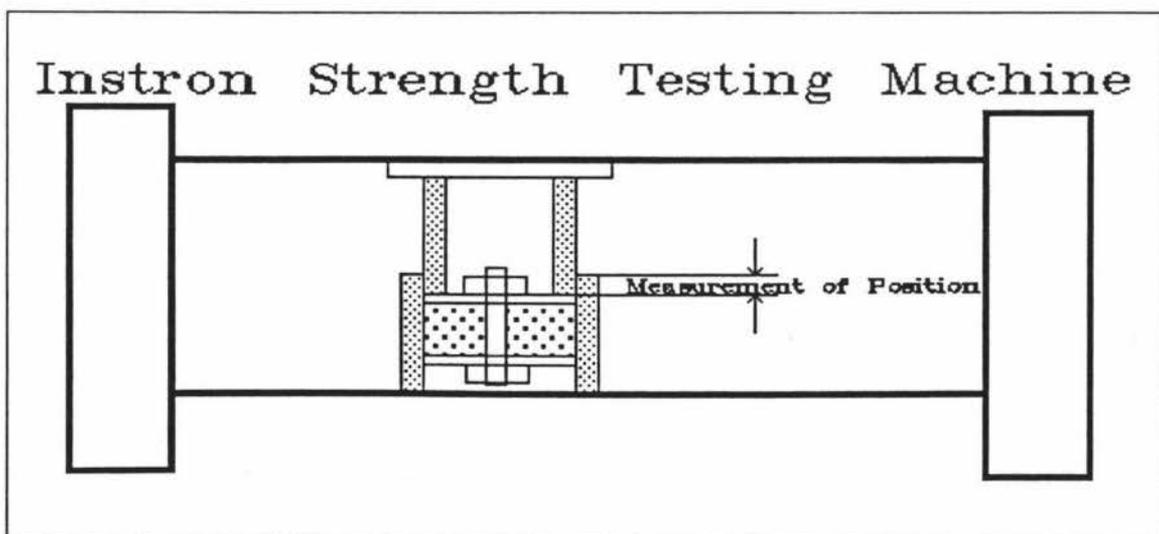
Figure 13. Locking Mechanisms



**Figure 14. Locking Bung**

The test sample was constructed from a natural rubber which was frozen with liquid air and machined to the required size. The prototype bungs were constructed using a readily available rubber hosing used on milking machines.

#### 4.8.1. Testing of Locking Bung Concept



**Figure 15. Test Arrangement of the Locking Bung**

To test the design a test unit was constructed. This consisted of the rubber bung being compressed between two washers by a nut and bolt. Two lengths of bung were tested, one was 40mm long, the other 50mm. The test piece was placed in a sample of fibre reinforced plastic tube and another tube placed against it (see Figure 15).

The bolt and nut were tightened by hand and the position of the bung was measured. The test piece was then placed in the Instron Testing Machine to determine the effectiveness of the bung. The tests were repeated using a section of aluminium tube.

Movement of the Locking Bung (mm)				
Force (N)	Reinforced Plastic		Aluminium	
	40mm	50mm	40mm	50mm
0	0	0	0	0
1000	0	0	0	0
1500	0.8	0.2	0.5	0.2
2000	--	0.4	2.4	0.7
2500	--	2.0	--	2.4

**Table 9. Bung Movement versus Applied Force**

#### 4.8.2. Results of the Bung Compression Test

There was movement during the application of the load. However, upon removal of the load in many cases the bung itself had not moved (see Table 9). The movement detected by the Instron was presumed to be a result of the bung compressing.

### 4.8.3. Conclusion of Bung Design

As can be seen from Table 9, there was no movement of the bung at 1000 Newtons (N) loading. At 1500N the movement was minimal for the 50mm long bung. There was not much difference in the performance of the reinforced plastic and the aluminium tube. The 40mm bung showed considerably less resistance to the applied force. It was decided to use the 50mm bung.

### 4.8.4. Prototype Locking Bung Design

Following the successful test of the sample bung, a prototype was built (See Figure 16). The first prototype used an 'O' ring to prevent the locking nut from rotating to ensure the compression of the rubber bung. The prototype of this design was found to be unsuitable, as to get a ring which provided sufficient resistance to turning, it was found that the resistance to sliding for adjustment was excessive. As an alternative to the 'O' ring, several wires ranging from a guitar string to a stiff stainless steel wire were used. These were also unsatisfactory as they did not provide sufficient resistance to the turning of the lock nut.

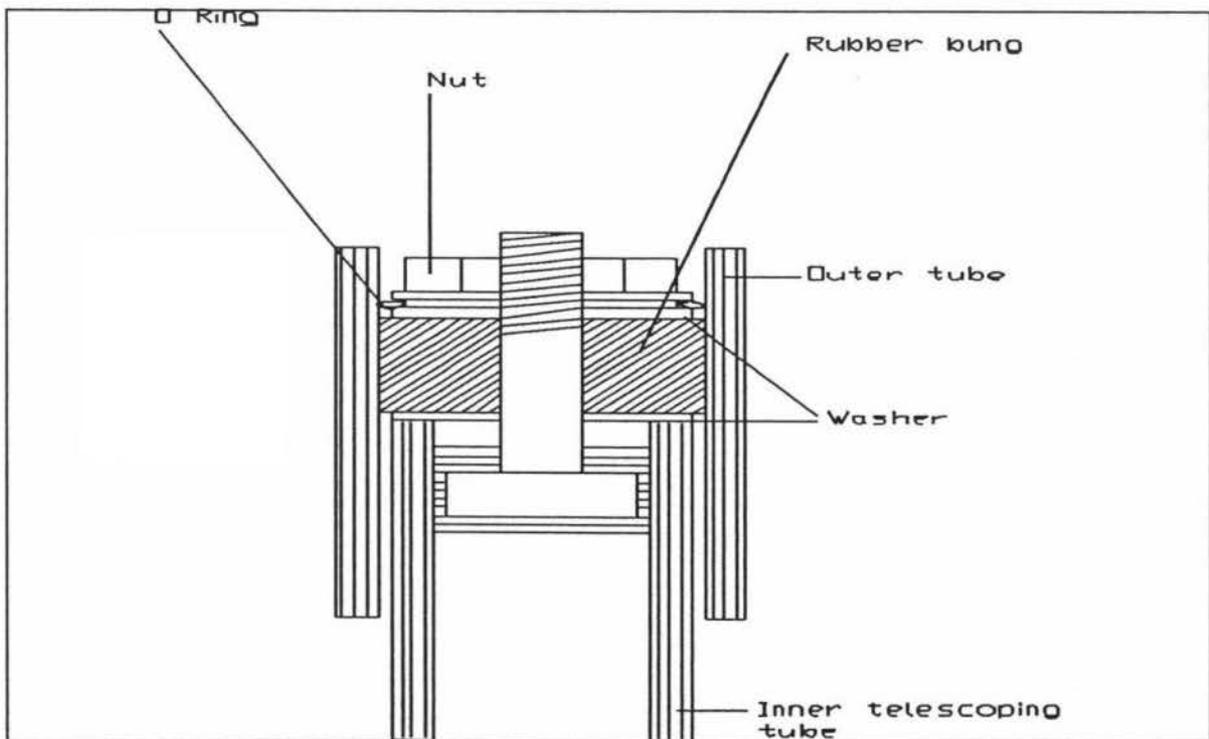
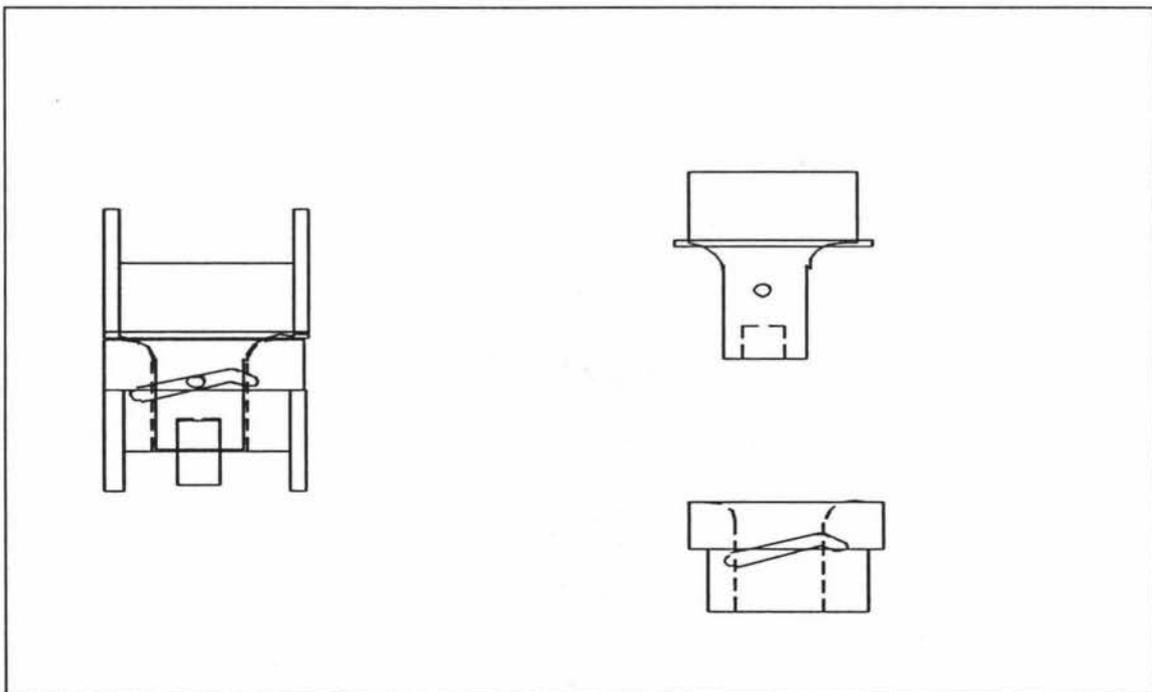


Figure 16. Locking Bung

At this time an alternative to the screw action for compressing the bung was sought. The design used a cam action to separate two sections of the adjustment mechanism which pulled a rod through the bung, causing it to compress (See Figure 17).

The first prototype had the cam action provided by a slot cut in the aluminium tube. This was unsuccessful as the aluminium was not able to withstand the forces applied by the pin.

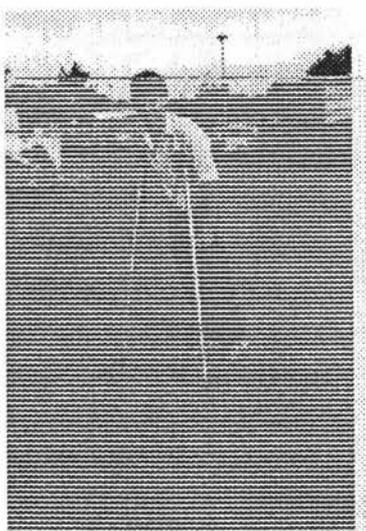
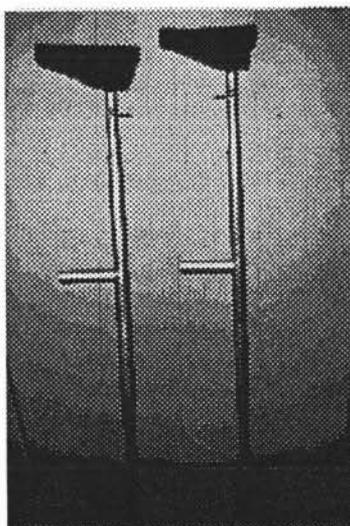
The second prototype utilised a machined plastic (Delrin) unit which was installed into the tube (see Figure 17). This unit operated very well, with the plastic bearing surface providing a very smooth action and the effect of the compression on the rubber bung resulted in an effective locking action. The disadvantage of the machined design was that as there was a thin section taking the full loading, it was vulnerable to failure. For the purposes of evaluation of the prototype testing, the internal section was constructed from stainless steel as opposed to plastic. The manufactured units required a helical milling operation for the slot. It would be proposed that in the final manufactured unit that the plastic parts would be injection moulded. This would mean that the plastic above the slot could be removed to



**Figure 17. Cam Action Unit for Locking Bung**

enable the unit to be made in a one piece mould. With this slight change in design it will also be possible to mould the 'pin' into the top section of the unit. This would have the effect of increasing the strength of the unit.

The prototype crutch was constructed from aluminium tube (see figure 18) with the axilla piece and hand piece welded on. The axilla piece was covered by a cloth backed foam to provide a more comfortable surface. It was initially intended to cover the hand piece with the same material but the need for a cover which would not slip made this too difficult.



**Figure 18. Prototype Axilla Crutch**

## 5.

### PROTOTYPE MECHANICAL TESTING

Firstly there was the need for a preliminary mechanical test to ensure the mechanical integrity of the device prior to its issue to a user. The mechanical testing was based on the Cyclic and Impact Load tests from the New Zealand Standard for axilla crutches (See Appendix B).

#### 5.1. Pre-Test Preparation

Prior to the mechanical testing the crutch was measured such that any deformation occurring during testing could be detected. Figure 19 details where the measurements were taken.

#### 5.2. Cyclic Loading Test

The axilla crutch was loaded with a vertical force of 0.5 times the design user's weight (duw) of 95Kgs 500,000 times at a rate not exceeding 100 applications per minute.

The force was applied through a block moulded to the shape of the handle and covered 75% of the length of the handle. The mounting block was centred on the handle. The point of impact of the crutch was constructed of particle board and inclined at  $10^{\circ}$  to the horizontal (see Appendix B for details on test method).

#### 5.3. Impact Loading Test

The crutch, while in the test rig for the Cyclic Loading Test was subjected to an impulse of 1.50 times the duw. The load was applied within a time duration of 10 msec. This test was repeated 10 times.

## 5.4. Results

At the completion of the tests, the crutch was measured again (see table 10). As the pre and post test measurements had not varied by more than 0.5mm the crutch was considered to have passed the test.

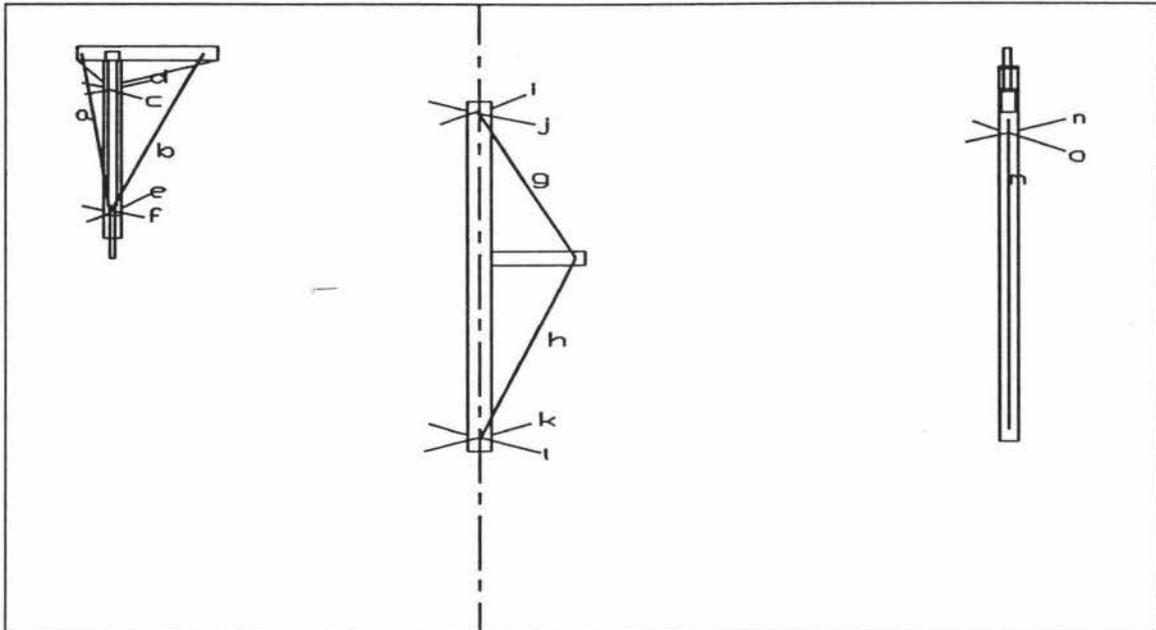


Figure 19. Measurements Taken

Measurement	Pre-test	Post-Test
a	354.0	354.0
b	385.0	385.0
c	25.3	25.3
d	25.3	25.3
e	25.3	25.3
f	25.3	25.4
g	366.4	366.5
h	460.5	460.5
i	31.8	31.8
j	31.8	31.8
k	31.8	31.8
l	31.8	31.8
m	705.0	705.0
n	25.4	25.4
o	25.4	25.4

Table 10. Pre and Post Test Measurements

## 6.

### HUMAN FACTORS TESTING OF PROTOTYPE

There were two stages to the field trials. Initially the crutches were issued to a long term user for a one week period. Based on the results of this trial, any necessary design modifications were made and the crutches were issued to short term users through the Palmerston North Hospital Accident and Emergency Department.

#### 6.1. Stage 1

The crutch was issued to the long term user (height:1.7m, Weight:90Kg) for a period of one week. The user was asked to record his impressions and comments on the crutch while using the crutch, and at the end of the week complete a questionnaire.

#### 6.2. Stage 2

The Medical Ethics Committee of the Palmerston North Hospital was approached for permission to field trial the crutches in the Accident and Emergency Unit of the Hospital. To gain permission the Author was required to submit an outline of the proposed work (see Appendix C), a consent form to be used during the trial and to fill in a questionnaire. It was very important that individuals undertaking to trial the new design of crutch were made aware of the fact that it was a prototype, that they did not have to take part in the trial if they did not wish to, and that they could pull out of the trial at any time with no detriment to their continued treatment.

Following the evaluation of the proposed trial and the prototype crutches by the Ethics Committee, a request was made to modify the design to provide a safety lock device which would ensure that the adjustment lock could not come undone during use. Modifications were made to the prototype to provide for the use of 'R' clips to work as secondary locks to ensure that the adjustment mechanisms would not come undone.

A mark was engraved along the length of the upper section to act as a guide to line the upper section up with a matching mark on the central section. This meant that with the lines matched, when the axilla piece was rotated to activate the lock, the axilla piece and the hand piece were lined up.

Axilla crutches are issued by the Accident and Emergency Department Orderly at Palmerston North Hospital. The Author worked with the Orderly in issuing the new design of crutch. The Author was responsible for explaining the purpose of the study and gaining the patients consent. The Orderly issued the patient with the new design of crutch, making the necessary adjustments, and with a conventional pair of crutches. The author then retrieved the crutches from the patient after periods from 3 days to one week, along with a completed questionnaire.

### **6.3. Results of the Field Trials with Long Term User**

When initially issued with the crutches, the user expressed some concern that as the lock was activated by a twisting action, they may unlock during use. It was explained that as the body weight was applied to the crutches the effect would be to hold the lock on as the pin which worked the cam action sat in a recessed notch. This was confirmed during use as at no time did the user experience any problems with the locks coming loose. The user found the crutches easy to use but thought that the prototype was slightly heavy. During use the user found the crutches to be:

- Secure
- Comfortable
- Slightly noisy
- Very easy to adjust
- Easy to use
- Easy to carry
- Easy to store

- Better and more attractive than the existing designs.

His comments on the prototype pair included:

- Stowed very easily in cars
- Based on previous experience, because of the exposed metal, they would be extremely difficult to use getting in and out of saunas.
- The weight and diameter of the crutch made them difficult to hold in one hand when standing, sitting or moving in and out of a car.

General comments included:

- Love the idea!
- Think the locking mechanism needs minor modifications.
- Would like to trial the "Plastic" ones.
- The rubber knob (ferrule) showed some signs of strain from turning.
- Handle diameter was right for my hands but I miss the "Stop" of "Normal" crutches, i.e. my hand could slide off the handle.
- Like the strength and "Solid" feel.
- Would prefer plastic or wood for the axilla piece as the fabric tended to catch on my clothing.

#### **6.4. Results of the Field Trial with Short Term Users**

As there is a limited group of people requiring the equipment being developed in this sector there is also a very limited number of individuals who are suitable and able to field trial the prototype. In the time allocated to the field trial only two suitable individuals were identified (Subject 1 - Height:1.88m, Weight:83Kg Subject 2 - Height:1.85m, Weight 75Kg).

The general feelings relating to the crutch were in accordance with the long term user's comments.

One problem did become apparent in that the upper section of one crutch had a tendency to come loose which resulted in the adjustment slipping. This was identified as the stud working loose from the acetal insert on the cam unit. This was fixed with locktite and the locking nut retightened. This appeared to correct the problem.

General comments included:

- The crutch tended to rattle.
- Some padding on the handle would be good.
- It felt 'freer' to use than the other [conventional design] crutch.
- It could do with height adjustment marks to make it easier to set both crutches to the same height.

## 7.

### DISCUSSION

This Thesis looked at two aspects of the product development process. Firstly, there was how the process could be applied to the design of equipment for people with disabilities. Secondly, there was the case study of the axilla crutch.

#### **7.1. The product development process for the axilla crutch**

The product development process worked well as a model for the development of an item of equipment for people with disabilities. An original premise for the work was a need for a high emphasis to be placed on on the market research and the field trial phases, the reality of the work was, however, while market research information was able to be collected, there was great difficulty in locating suitable subjects for the field trials.

A number of problem areas resulted in the time for the study becoming quite extended. These problem areas were:

- Lack of research information. The area of equipment for people with disabilities is small. This has meant that there has not been a lot of research carried out and published in contrast to many other industries.
- Lack of record keeping. As there is, generally speaking, very little record keeping of the issue of this type of equipment, it is very difficult to determine information on the market size.
- Lack of anthropometric data. As there has not been an anthropometric study of the New Zealand population carried out, it is very difficult to determine the size requirements of the population. In the area of equipment for people with disabilities, there is a lack of anthropometric data even in countries which have carried out anthropometric studies as they tend to study the average population and the the disabilities groups are only a small percentage.

- **Ethics.** When it comes to the field trial, the safety and wellbeing of the patients is paramount. This means that the Ethics Committee must study the proposed work carefully to ensure that the research will not adversely affect the subject's treatment.
- **Test population.** The market size within this sector is relatively small. The disabled population as a whole is estimated to be approximately 10% of the overall population. This carries over to the numbers of people readily available for the field trials of the prototype design. This can be seen by the fact that within the time period allocated for the field trials, only three suitable candidates were identified.

Looking at the overall process which was proposed for the design of the axilla crutch (see Figure 5) the following comments could be made.

#### **7.1.1. Standards for Walking Aids.**

The work for the Standards provided valuable secondary data for the development of the new crutches. It also provided some excellent information for the product constraints.

The survey performed for the preparation of the standard provided a considerable amount of the information needed and helped focus the questionnaire required to gather the primary data.

#### **7.1.2. Product Idea**

The work performed for the Standards provided the initial idea through highlighting an area for which there were difficulties with the existing equipment. This based on the results of interaction with individuals both using and prescribing the equipment provided the product idea.

#### **7.1.3. Literature Survey**

As has been stated earlier, there is a great dearth of information in this area. This lack contributed greatly towards the difficulties experienced in this project.

#### **7.1.4. Technical Requirements.**

The technical requirements were hard to determine in the face of the shortage of information. Some basic concepts came out of the literature survey, but more information was provided by the survey performed for the development of the New Zealand Standard for Walking Aids and the Market Survey.

#### **7.1.5. Market Survey**

There were difficulties with the response to the market survey as very little information is recorded in this area. There were, however, some basic points which appeared to be consistent across the country, and these points in particular provided the information necessary for the design.

#### **7.1.6. Product Concept**

As a result of the literature survey and the market survey, a number of points were made and these are summarised on page 33.

#### **7.1.7. Product Design Specifications**

The information from the surveys provided much of the information required to develop the product design specification.

#### **7.1.8. Product Constraints**

From all the previous work, some product constraints were drawn up.

#### **7.1.9. Prototype Design**

Based on the requirements previously stated, several concepts were looked at until the prototype for testing was finally constructed. As the axilla crutch is a relatively simple item of equipment in engineering terms, most areas of the prototype design were relatively simple with the major effort going into the design of the adjustment method.

### **7.1.10. Theoretical Evaluation**

Prior to the actual construction of the prototype, it was important to calculate what should happen to the crutch, physically. This was done in conjunction with the materials selection.

### **7.1.11. Prototype Construction**

Some compromises to the 'ideal' design were made in view of the pressures of the time frame for the project and the available skills. In particular, the change from the original desire to construct the prototype in plastic to constructing it in aluminium as the properties of this material were better understood.

### **7.1.12. Prototype Evaluation**

This is an important area of the work. The evaluation has to be local, and above all else safe. It is the mechanical and human factors evaluation which will prove the design. In view of the small market population it was difficult to find suitable subjects for the human factors evaluation. The results of the evaluation of the three subjects, however, were quite consistent.

The design of the axilla crutch was taken only this far. The constraints of time prevented the project being taken into the production area although some aspects a proposed method of construction are discussed in the next section.

## **7.2. The axilla crutch**

The final design of the axilla crutch performed well in the mechanical evaluation and received positive comments from the user trials. To this extent it met the design requirements for it. In the process of developing the device various compromises were made.

The prototype was made from aluminium as opposed to the plastic which was originally desired. Having proven the design concept, the Author feels that it would be feasible to take the next step and design with plastic tubing.

The cam action unit was machined from stainless steel rather than moulded in plastic. This need to be done as it was not feasible to make a moulded unit for a prototype. The Author believes that the locking unit as designed for this purpose could be used in many other areas (such as camera tripods or tent poles) which would mean a much larger market for the unit. The benefit of this would be to make it cost effective to tool up for moulding this component. The advantages of molding this component would be in the cost per unit and the molding process itself would produce a much stronger unit than one which has been machined.

As the field trial was carried out with a small number of people it is recommended that further work is carried out in this area. The comments and evaluations from the users were positive and based on this, combined with the market research showing a need for crutches which adjust for the taller users, the Author feels that there would be value in persuing the design further.

Some further work could be carried out in the design of the ferrules and the interface between them and the bottom stem as highlighted by the long term user.

A further stage which could be looked at is the protection of the concepts resulting from the project in terms of Patent protection. There are two basic ideas which could be protected. These are:

**Idea One:** A method of locking two telescoping tubes by the use of a compressible rubber bung.

The claim could define this invention as: A means of locking two telescoping tubes by a rubber bung designed to match the inside of the outer telescoping tube, constrained by washers of the same shape as the bung, the complete unit having a co-axial hole through which a rod attached to the outermost washer passes and is attached to an assembly in the inner tube which provides for a cam action which would, when activated draw the rod through the bung assembly resulting in the rubber bung compressing and locking against the inside of the outer tube by virtue of the friction produced by the compression.

**Idea Two:** A single stem axilla crutch utilising an adjustment system based on the 'Locking Bung' principle.

The claim could define the invention as an axilla crutch consisting of three parts. An upper component which consists of an axilla piece and a tube which is designed to slide into a matching tube of the central component and which contains the locking bung method of fixing the telescoping action of adjustment. A central component which consists of a hand piece and a tube to receive the upper component and a tube to receive the lower component. A lower component which consists of a tube which is designed to slide into the matching tube on the central component and which contains the locking bung method of fixing the telescoping action of adjustment and an interface at the lower end of the component to receive a ferrule.

It is strongly recommended that before the Patent protection step is made that the assistance of a Patent Attorney is sought.

## 8.

### CONCLUSION

The product development process is a model for a method of developing a product from its initial concept stage through to market production.

This process has been used for many years in the consumer goods areas. It is only very recently that moves have been made to utilise the process in the development of equipment for people with disabilities. This has been partly as a result of the costs involved in research and the difficulties experienced in absorbing these costs in an industry which has a small market.

As a result of economic changes within New Zealand and the moves to deregulate trade with Australia, the possibility of using the product development process within the disability sector is becoming a reality.

This thesis has described the product development process, and by the use of a case study, the design of an axilla crutches, endeavoured to see how this process would function for an item of equipment for people with disabilities.

An initial premise was that there would be the need for a much greater emphasis to be placed on the market research and field trials areas of the development. The market research stage was not necessarily carried out in a manner more rigorous than one would expect of this stage, and provided sufficient information for the design and development of the prototype. The field trial stage was significantly hampered by a lack of suitable subjects for the trials. This is a difficulty which would probably extend in all equipment development for the disability sector.

In conclusion, the usefulness of the product development process has been shown in other industries, the research performed for this thesis has shown that the stages in the development process are applicable to equipment for the disability sector. Based on these two points, the Author concludes that the product development process is feasible and desirable for equipment for the disability sector.

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## APPENDIX A: Walking Aids Questionnaire

### Factors and Level of Importance

Factor	not important			important	
Cost	<input type="checkbox"/>				
Weight	<input type="checkbox"/>				
Adjustment Range	<input type="checkbox"/>				
Durability	<input type="checkbox"/>				

	Yes	No
Is it important that crutches can be used in either hand	<input type="checkbox"/>	<input type="checkbox"/>
Is the existing axilla piece acceptable in its design	<input type="checkbox"/>	<input type="checkbox"/>

Is there a lack of crutches for people in the following height ranges:

< 1.5m	<input type="checkbox"/>	<input type="checkbox"/>
1.5-1.65m	<input type="checkbox"/>	<input type="checkbox"/>
1.65-1.8m	<input type="checkbox"/>	<input type="checkbox"/>
> 1.8m	<input type="checkbox"/>	<input type="checkbox"/>

For users over 1.8m tall what would be their

average weight	[	]
maximum weight	[	]

## Construction

Are existing crutches generally?

too light       OK       too heavy

Yes      No

Are crutches sturdy enough in their construction           

If no, where is the most common site of breakage?

## Usage

In the past 12 months approximately how many crutches would have been issued in the following groups:

age	Male	Female
5-10 years	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
11-15 years	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
16-20 years	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
21-25 years	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
26-30 years	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
31-40 years	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
41-50 years	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
over 50 years	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

What are the most common causes leading to a patient using axilla crutches

What is the average time that a patient would use a pair of axilla crutches for

What percentage of users would use the axilla piece for:

0%-24% 25%-49% 50%-75% 75%-100%

stability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
weightbearing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
both	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

What percentage of users would require a sculptured handpiece

Any other comments about axilla crutches you would like to make:

## Appendix B Excerpt From New Zealand Standard For Axilla Crutches

NZS 5831:Part 3:1989

### A2.3

Each measurement is to be made to a resolution of 0.1 mm.

#### A2.3.1

These measurements are to be made prior to and at the completion of the mechanical testing.

#### A2.3.2

##### *Acceptance criteria*

The before and after measurements must not vary by more than 1 mm.

### A3

#### Cyclic loading test

#### A3.1

##### *Procedure*

##### A3.1.1

The axilla crutch shall be cyclically loaded with a vertical force of 0.50 times the design user weight (duw) 500 000 times at a rate not exceeding 100 applications per minute.

##### A3.1.2

The force shall be applied through a block moulded to the shape of the handle suitably protected with leather, and covering 75 % of the length of the handle. The mounting block shall be centred on the handle. Fig. A1 shows a suggested test rig to perform the test. The point of impact of the base of the device shall be constructed of particle board and inclined at 10° to the horizontal.

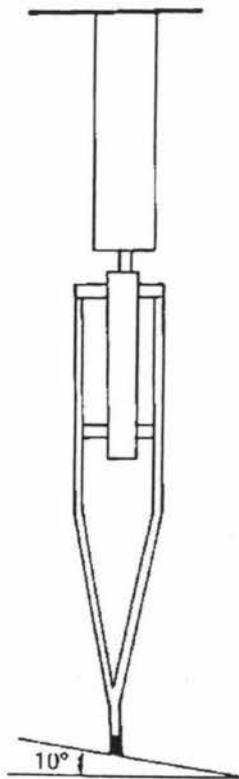


Fig. A1  
SUITABLE TEST RIG FOR CYCLIC AND IMPACT LOADING TESTS

## NZS 5831:Part 3:1989

**A3.1.3**

There shall be no discernible deformation or damage or permanent wear which could impede the performance of the device. (For pre and post test measurement and acceptance criteria refer to A2.2 and A2.3.)

**A4****Impact loading****A4.1**

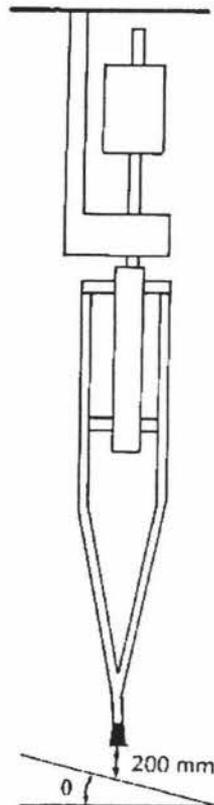
The device, while in the test rig specified in A3.1.1, shall be subjected to an impulse of 1.50 times the duw. There shall be no discernible deformation or damage or permanent wear which could impair the performance of the device. (For pre and post test measurement and acceptance criteria refer to A2.2 and A2.3.)

**A4.2**

The loading shall be applied over a time span of no more than 10 milliseconds. This test shall be repeated 10 times.

**A5****Ferrule friction test****A5.1**

The device shall be fitted into a test rig capable of applying a load of 0.50 times the duw through the handle. Fig. A2 shows a test rig suitable for this purpose. The device shall be dropped vertically through a height of 200 mm onto a sloping surface constructed of particle board. The angle of the slope is increased in the forward direction until the device slips at least 50 mm down the slope.



**Fig. A2**  
**SUITABLE TEST RIG FOR FRICTION AND SURFACE MARKING TESTS**

## **Appendix C: Submission to Medical Ethics Committee**

### REQUEST FOR APPROVAL FOR FIELD TRIALING OF

### A NEW DESIGN OF AXILLA CRUTCH

Principal Investigator: P. B. Challis B.E.  
New Zealand Disabilities Resource Centre

Financial Arrangements: There are no financial arrangements for any aspects of the study.

#### **Introduction**

At present the Author is undertaking a course of study for a Masters Degree in Technology (Product Development) at Massey University. The focus of the Thesis is the product development process as applied to the area of equipment for people with disabilities.

#### **Case Study**

The processes are highlighted through the use of a case study. This has been the design of an axilla crutch. This item of equipment was chosen for a number of reasons:

- At the time the thesis was being set up, the Author was involved in the development of the New Zealand Standard for walking aids.
- The Author had been involved in a study of walking aids within New Zealand which provided much of the information need while highlighting problems with the range of equipment on the market.
- The device itself is sufficiently simple for it to be feasible to design and construct within the terms of the thesis.

## **Present State of Development**

The background design work has been completed and a prototype has been constructed. The prototype has been developed to suit the needs of the taller and heavier group of users, for example male sports injuries. For this reason the prototype is heavier than conventional devices.

There are two stages to the evaluation of the prototype:

- Mechanical Evaluation
- Human Factors Evaluation

### **Mechanical Evaluation**

This stage has been carried out. Information on this part is included.

### **Human Factors Evaluation**

It is proposed that this work is carried out in two phases. Firstly a long term user is to use the prototypes and fill in a questionnaire. This has been completed. A copy of the questionnaire is included as an appendix. Secondly, several short term users need to use the equipment and then move onto the usual equipment. A questionnaire will be issued to the patients to fill in. This will provide subjective information on a comparison between the new design and existing designs.

The reason for writing to the committee is to seek approval for the field testing of the new design of crutches with hospital patients. The concept has been discussed with Monica Huisman, and she has agreed to assist.

### **Prototype Testing**

There were two aspects of evaluation of the prototype crutch. Firstly there was the need for a preliminary mechanical test to ensure the mechanical integrity of the device prior to its issue to a user. Secondly there was the field trial to test for ease of use, function and comfort.

## **Mechanical Testing**

The mechanical testing was based on the Cyclic and Impact Load tests from the New Zealand Standard for axilla crutches.

### **Pre-Test Preparation**

Prior to the mechanical testing the crutch was measured such that any deformation occurring during testing could be detected. Figure 14 details where the measurements were taken.

### **Cyclic Loading Test**

The axilla crutch was loaded with a vertical force of 0.5 times the design users weight (duw) of 95Kgs, 500,000 times at a rate not exceeding 100 applications per minute.

The force was applied through a block moulded to the shape of the handle and covered 75% of the length of the handle. The mounting block was centred on the handle. The point of impact of the crutch was constructed of particle board and inclined at 10o to the horizontal.

### **Impact Loading Test**

The crutch, while in the test rig for the Cyclic Loading Test was subjected to an impulse of 1.50 times the duw. The load was applied within a time duration of 10 msec. This test was repeated 10 times.

## **Results**

At the completion of the tests, the crutch was measured again. As the pre and post test measurements had not varied by more than 0.5mm the crutch was considered to have passed the test.

Measurement	Pre-test	Post-Test
a	354.0	354.0
b	385.0	385.0
c	25.3	25.3
d	25.3	25.3
e	25.3	25.3
f	25.3	25.4
g	366.4	366.5
h	460.5	460.5
i	31.8	31.8
j	31.8	31.8
k	31.8	31.8
l	31.8	31.8
m	705.0	705.0
n	25.4	25.4
o	25.4	25.4

Pre and Post Test Measurements

### Human Factors Testing

There will be two stages to the field trials. Firstly it will be issued to a long term user for a one week period. Based on the results of this trial, any necessary design modifications will be made and two pairs of the crutches will be made and issued to short term users through the Palmerston North Hospital Physiotherapy department.

The crutches will be issued through the usual prescription process of the Physiotherapy Department to patients who have provided written approval to be involved in the testing programme. Both the prescribing therapist and the user will be issued with questionnaires.

## ISSUING OFFICERS INSTRUCTIONS AND QUESTIONNAIRE

### Fitting Instructions

1. Remove the 'R' clips.
2. Release the adjustment locks. There are two adjustment locks. These are just below the axilla piece and just above the ferule. They are released by holding the tube on either side of the adjustment and twisting in a clockwise direction.
3. Adjust the height of the handgrip by sliding the bottom tube inside the handle section of the crutch. Lock in place by holding the bottom tube on either side of the adjustment lock and twisting in an anti-clockwise direction.
4. Adjust the height of the axilla piece and lock in position.
5. Replace the 'R' clips.

## ISSUING OFFICER'S QUESTIONNAIRE

Questionnaire Number \_\_\_\_\_

Date \_\_\_/\_\_\_/\_\_\_

### User Information

Sex \_\_\_ Age \_\_\_ Height(m)\_\_\_\_\_ Weight(Kg)\_\_\_\_\_

Reason for using Crutch: \_\_\_\_\_

Time using the crutch (days): \_\_\_\_\_

### Crutch Information

<b>Axilla Piece</b>	Yes	No
Was the axilla piece lock easy to operate.....	[ ]	[ ]
Was the axilla height easy to adjust for the user.....	[ ]	[ ]

### Handle

Is the geometry of the handle and the shaft comfortable and easy to use.....	[ ]	[ ]
---	-----	-----

### Lower Shaft

Was the lower shaft lock easy to operate.....	[ ]	[ ]
Was it easy to adjust the height of the handle to suit the user.....	[ ]	[ ]

### General

Please tick the box which most closely expresses your opinion of the attribute under question. (e.g [ ] [ ] [ ] [ ] [ ])

1. Is the construction of the crutch:

Too light		Just right		Too heavy
[ ]	[ ]	[ ]	[ ]	[ ]

Too weak		Just right		Too strong
[ ]	[ ]	[ ]	[ ]	[ ]



## CONSENT FORM

This axilla crutch has been designed as part of Masters degree course in Technology. It has already undergone preliminary mechanical evaluation and an initial user trial. It is now being tested by short term users.

The process of this testing is for you to be issued with two pairs of crutches, the new design and the conventional set used by the Hospital. You are asked to use both pairs to enable a comparison to be made and a questionnaire filled in. You are under no obligation to take part in the field trial and can stop using the new design of crutches at any time without prejudice to your continued treatment by the Hospital. You need only contact the investigator if you wish to stop and arrangements will be made for the new design of crutches to be collected. At the completion of the trial time the investigator will collect the crutches from you, and you will complete your time with the assistance of the conventional crutches as normal, and they are to be returned in the normal way.

I ..... understand and consent to take part in the study on the basis of the information provided. Any questions that I had have been answered to my satisfaction and I understand that I may ask further questions at any time. I also understand that if I choose to withdraw from the study that it will not be held against me.

Signed.....

Witness ..... (other than investigator)

Date \_\_\_/\_\_\_/\_\_\_

Statement by the Investigator

I have discussed the study with .....(Patients name) and explained the benefits and alternatives with them.

## USER'S QUESTIONNAIRE

Questionnaire Number \_\_\_\_\_

Date \_\_\_/\_\_\_/\_\_\_

### Introduction

The following questions are divided into two main areas. Firstly there are questions on the basic design of the crutch. These cover the questions of construction and adjustability. These are followed by questions relating to the performance of the crutch in use.

Principal Investigator: Brent Challis B.E.  
 Phone 62-311 during the day  
 68-788 during the evening

### Construction and Adjustability

<b>Axilla Piece</b>	Yes	No
Is the axilla piece lock easy to operate.....[ ]	[ ]	[ ]
Is the axilla height easy to adjust.....[ ]	[ ]	[ ]
Did the adjustment show any sign of slipping.....[ ]	[ ]	[ ]

### Handle

Is the handle comfortable.....[ ]	[ ]	[ ]
-----------------------------------	-----	-----

### Lower Shaft

Is the lower shaft lock easy to operate.....[ ]	[ ]	[ ]
Was it easy to adjust the height of the handle.....[ ]	[ ]	[ ]
Did the adjustment show any sign of slipping.....[ ]	[ ]	[ ]

## General

Please tick the box which most closely expresses your opinion of the attribute under question (e.g     ).

1. Do you think the crutch is:

Too Heavy	<input type="checkbox"/>	<input type="checkbox"/>	Just right	<input type="checkbox"/>	<input type="checkbox"/>	Too Light	<input type="checkbox"/>
Too weak	<input type="checkbox"/>	<input type="checkbox"/>	Just right	<input type="checkbox"/>	<input type="checkbox"/>	Too strong	<input type="checkbox"/>

## Use

2. When using the crutch did you find it:

Not very secure	<input type="checkbox"/>	Very secure				
Not very comfortable	<input type="checkbox"/>	Very comfortable				
Very noisy	<input type="checkbox"/>	Not noisy				
Not easy to adjust	<input type="checkbox"/>	Very easy to adjust				
Not easy to use	<input type="checkbox"/>	Very easy to use				
Not easy to carry	<input type="checkbox"/>	Very easy to carry				
Not easy to store	<input type="checkbox"/>	Very easy to store				

