Development of low cost femoral thigh prosthesis and this technology transfer process

Carlos Eduardo Sanches da Silva, Carlos Henrique Pereira Mello, André Luiz Coutinho, Carlos Eduardo Martins de Oliveira
Universidade Federal de Itajubá
e-mails: sanches@unifei.edu.br; carlos.mello@unifei.edu.br; andrebidu@hotmail.com; caed@bol.com.br

Abstract: This article describes the development of a philanthropic femoral thigh prosthesis which meets the following features: quality; production limitations; low cost and; large scale production. It's a research developed specifically to aid thousands of dismembered victims of the civil war from the African country of Angola. Such femoral thigh needs to be manufactured in Angola, due to basically the need to adapt the prosthesis to the anthropometry of the patients, to avoid expenses with importation and the creation of new job posts. Therefore, it is also developed the manufacturing process and a proposal of transferring these technology to Angola.

Keywords: prosthesis, technology, product and process development.

1. The product context

The University research has expanded itself considerably in the last decades, furthermore its contribution to the total research effort of a country is a clear evidence of the diversity which characterizes the society in which it is inserted (WEBSTER, 1994; SCHUETZE, 1996; CHAUI, 2003; TONOLLI Jr. et al., 2005).

WEBSTER (1994) points out that the universities aid to the nations and even humanity, including public security, quality of life, health, environment and economical competitiveness, it may be particularly obtained by the creation and socialization of knowledge, specially with the development of new technologies. The essence, which drives the development of this research is the prerogative that developing new products with the participation of the university may improve the life of the less fortunate population.

War is a constant in the world, and its ill consequences are usually experienced by the population. An example of this unbalance is the African country of Angola, in which the civil war has prolonged itself for many years, severing numerous lives and mutilating thousands of others, establishing absolute chaos. The majority of the people lose their capacity to work due to the war that leaves irreversible physical impairments, as it is clearly shown in the following statement (PESTANA, 2007):

"Late night, the village slept with the exception of a few goats that perceived the strange movement. Shadows came down the mountains and wandered from house to house, leaving small packages on the doormats. Moments later, shotguns spit fire. M-16 rounds were shot towards the humble clay buildings with hay ceilings. Bernadete Joaquina, startled, ran out of her house. In the dark, she did not perceive and step on her package: a land mine. The explosion severed her foot. With no money to afford the public health care, it took her a long time before a doctor even got to see her. It took her so long that when the doctor arrived he had no other option but to amputate her rotten right leg". That was in 1998, in Huambo, central region of Angola. Today, at 21, Bernadete lives her life with her newly born baby on the Refugees Center from the city of Benguela, 500 kilometers from the capitol Luanda. She and other four thousand people pile up inside an old school turned into a slum. The Angolan civil war is about to make its 27th birthday along with frightening numbers: more than 1,5 million people killed (the population is 12 million) and nearly 3 million are refugees either inside or outside the 1.246.700 km^2 of territory (larger than France). Just like Bernadete, Simão Francisco Cabanda, ex-combatant of the Angolan Armed Forces was also victim of a land mine in 1986. Due to lack of medical aid he also had his leg amputated. He used to get a US$2.00 monthly financial aid. It's been three years since he last got any financial aid from the state. In 1993, he moved alongside his family and other 45 thousand people to a refugee camp in the province of Bengo and today knits hay carpets to survive."

2. Research objective

Angola has the world's largest population of amputees, around 80,000, and with increasing tendencies, once there are 20 million land mines still buried under its soil. In an official report (2000), UN reported that a land mine costs between US$ 3.00 and US$ 25.00 to be armed and around US$ 300.00 and US$ 1000.00 to be disarmed and removed.

The land mines get in the way of agriculture, transportation, provoke rural exodus and its victims lose the capacity to move. Most of the land mines installed in Angola were manufactured in Brazil, USA and the former Soviet Union.

On the city on Mexico there is a rehabilitation center, maintained by the Red Cross International Committee (RCIC), that has capacity of treating amputees from various provinces. The institution makes monthly, an average of 50 to 65 prosthesis depending on the number of patients which come to the place, there's been weeks which 15 amputees were rehabilitated.

Considering the UN data, there are 80,000 amputees in Angola, the rehab center would have to work another 100 years, these comes disregarding the increase in the number of patients due to mines still under Angolan soil. It is very common that the population uses rudimentary methods to build prosthesis. In order to get by, it is used even chunks of wood, rags and ropes in a rudimentary improvisation.

Many works emphasize the development of thigh prosthesis as a contribution for the enhancement of the quality of life for the amputated so they will have, as close as posible, an almost normal adjustment to society (SIMÕES; MARQUES, 2005; KAPTI; YUCENUR, 2006; WOOLSON; DELANEY, 1995; NICOLELLA et al., 2006; HOWCROFT et al., 2006; MATHIAS; TABESHFAR, 2006).

In such a context, the research aims to:

- Develop a philanthropic prosthesis which meets the features: quality, production limitations, low cost and large scale production;
- Elaborate and describe the production process of the prosthesis;
- Available a means of transferring the process technology to Angola.

3. Theory basis

In elaboration and project of a product, either new or old, to the market, one must have as a goal the satisfaction of the consumer's demand, there needs to be well defined the product's basic benefit. The conceptual project of a product starts from theses basic benefits and market needs (BAXTER, 1998).

In order to achieve success in the conceptual project, there are certain stages to be followed as in Table 1.

The conceptual development stages proposed by Baxter (1998) are used on the development of the low cost femoral thigh prosthesis. The importance of creativity on the creation of concepts is described by Moorman and Miner (1998), and also Carvalho and Back (1999).

4. Development of the low cost femoral thigh prosthesis

4.1. Objectives of the conceptual project – General needs of the amputees

The reality that the physically impaired people live on developed countries is way different from those living in poor countries. On these countries there is usually an (insertion) politics of the physically impaired into the market, through fixed cottas inside companies. There is also a great infrastructure of support: improvements on sidewalks and buses to aid locomotion, ramps, etc.

In Germany, a country which stands out for its state of the art technology on bioengineering, it is easier to the impaired to gain access to new treatment technologies: Sophisticated apparatus, effective medical assistance and rehabilitation through physiotherapy. A femoral thigh prosthesis may cost from US$ 2000.00 up to US$ 6000.00.

To better approach the subject, let's treat the prosthesis as a product and the amputated as a costumer.

In light of the great social differences, cultural and economical, we noticed that the profile of the costumers from rich countries is totally different from costumers from poor countries such as Angola. Consequently, the product won't be the same.

Below, on Table 2, there are the main needs of each costumer and what each expects from a femoral thigh prosthesis, according to an interview performed in February, 2002, with the (ortesista) Luciano da Silva an the (ortesista) Manoel Leandro da Silva (both from Rita de Cássia Orthopedic Clinic in Taubaté, São Paulo's country side) and the technical catalogs from OTTO-BOCK (largest orthopedic supplier in Germany).

Based on Table 2, there was established the objectives of the conceptual process, which consisted on the compliance of the general needs of the Angolan amputees.

Table 1. Stages of the conceptual project and expected result (BAXTER, 1998).

	Stage 1	**Stage 3**	**Stage 3**
Conceptual project	Objectives of the conceptual project.	Creation of doable concepts.	Selection of the concepts according to the project's specifications
Result	Proposition of the basic benefit, within the goals established on the project specification.	Creation of many concepts.	Selection of the best concept comparing to the project specifications.

Table 2. General needs of the amputees.

Developed countries	Angola
Lightness	Minimal threshold
Durability	Durability
Resistance	Resistance
Flexibility	-
Impact absorption	-
Versatility of movement	Average versatility of movement
Sports practice capability	Basic ergonomics
Comfort	Minimal comfort
Edgy design (esthetic)	No need of esthetic
Easy adaptation	Good adaptation
Easy acquisition	Low cost
Sociability (social insertion)	Reacquisition of work capability

4.2. Creating the concepts

Before any concept was sketched, it is necessary a small explanation on: the components which usually are used on all femoral prosthesis, prosthesis and vacuum forming.

4.2.1. Prosthesis components

No matter the cost or the technology used, there are certain components which are basic and common in all of the prosthesis:

- Donning: part of the prosthesis which is used to accommodate the coto;
- Coto: part of the leg where the amputation was made:
  - Above the knee – from the amputated region to the isquio bone.
  - Below the knee – from the amputated region to the knee.
- Body: element which replaces the lower leg (when the amputation is below the knee) or the leg itself (when it is above the knee). On the last scenario the body of the prosthesis usually have a mechanical knee;
- Foot: is the lower extremity of the prosthesis which supports the set. Replaces the foot which was amputated;

Connection elements:

- Foot - Body: element that connects the foot to the body of the prosthesis, might have or not a controlling device;
- Donning - Body (Alignment Tool): element which connects the donning to the body of the prosthesis which is responsible not only for the assembly of the set but also for the alignment of the prosthesis.
- Sole: element placed under the foot, that protects it.

4.2.2. Prosthesis alignment tool

The Alignment Tool of the prosthesis is intended to correct the imperfections of the coto (piece left from the severed limb), i.e., if the coto of the amputee is crooked (weather due to a bad amputation or even a physical problem of bad bone structure), the prosthesis can not be crooked. There is a natural tendency from the prosthesis to follow the inclination of the coto, therefore, without the alignment tool it wont align itself to the individual gravity center.

Basically, there are four problems which may occur on prosthesis due to the bad alignment of the coto. These problems have the following names:

- Abduction - leg inclined to the outside of the individual's body center;
- Adduction - leg inclined to the inside of the individual's body center;
- Flection - leg inclined to the front of the individual's body center; and
- Extension - leg inclined to the back of the individual's body center.

The prosthesis alignment is a critical stage which affects a lot the process of concepts creation. Both in the national market as in the world market there are some components which were specially developed to perform such task, and which meets the needs to their full extent. However, these components are fairly expensive covering a considerable part of the final price of the whole prosthesis. Any conception formulated in other to replace or enhance this component will have only one aim: cost reduction.

4.2.3. Vacuum forming

The use of vacuum forming has been very accepted during the last decade, being applied in various applications and new technologies. Each day more and more products use in their manufacturing process this technique, making the technology more and more affordable.

This technique consists basically in changing the geometry of a thermoplastic material (which alters its shape when heated), using vacuum or suction. A plate of the chosen material (example polypropylene) é heated and placed above the matrix, which will determine its final geometry. The air fills the cavity between the plates and the matrix is sucked out, making the material shape itself to the molds of the matrix. After cooling down the material will retain the new geometry acquired in the process. That's why this technique can also be called molding.

The molding allows us to: decrease the weight of the product considerably, once it uses polymers; develop complex geometries; produce in large scale (one matrix can be used to model lots of parts); reduce the products price; accessible technology; for the aforementioned features, most of the conceptions were made considering the use of such process, mainly because of the chance of making a low cost product.

4.2.4. Created conceptions

To better perform this stage, it was decided to split the elements which build the prosthesis and come up with specific conceptions for each one of the components. So that then final prosthesis conception will be made by the selection of the best conceptions of each component.

There was no difficulty in creating and analyzing the concepts on the early stages of the project, only the connection elements, which demanded more dedication from the group. Lots of the created conceptions during the project were not approved by the orthesyst and the prosthesis expert (mentioned on item 4.1.), nonetheless, others were studied, approved and even made it to the final prosthesis.

The conceptions created during the process, as well as its features and selection criteria, are described on item 4.3.

4.3. Screening (selecting, selection) the conceptions

All the conceptions were created meeting the characteristics of quality and production limitation. Weather it is a selected conception or not, they all meet the durability, resistance and lightness requirements.

Aiming the satisfaction of both quality and production limitation demands, the factor which most influenced the selection process was the product cost (characteristic of extreme importance regarding a philanthropic product). On Table 3, the main conceptions created to the respective components.

4.3.1. Donning selection: modeled polypropylene donning

The donning made of acrylic resin not only is more expensive it is also the on with the highest amount of difficulties during the production process. The modeled Surlyn polypropylene donning (specially to orthopedic purposes for its flexibility) is obtained the same way as the regular polypropylene, nevertheless it costs approximately three times more and it is also less common in the market. The polypropylene donning meets all the needs and is the most accessible conception.

4.3.2. Body selection: aluminum connection bar

The Iron-Titanium alloy connection bar is used in most of the prosthesis, both national and imported for its excellent resistance (essential feature for this component), but it is also the most expensive conception. At first, the wooden bar conception seemed to be the best option, for it is the lowest cost conception and with the best accessibility. Nevertheless a better analyses showed a flaw in this conception, which is the durability, once the prosthesis will be subject to various variations on its environment such as weather, humidity, different soils, etc… It was decided then to go with the aluminum connection bar in spite of its cost being higher then the wood, it meets all the requirements.

4.3.3. Selection of the foot: modeled polypropylene foot

The carbon fiber foot (most resistant of all conceptions) and the rubber one, do not demand production, for their easy accessibility on the market. They would be good option if only they didn't have such a high cost. The modeled polypropylene foot meets all the requirements of resistance, impact absorption and is the most economical viable option.

4.3.4. Selection of the connection foot-body: fixation screw

It was chosen to extinguish the connection element and fixed the set with a screw and a pressure (bolt), reducing the overall cost with the absence of this component.

4.3.5. Alignment tool selection: modeled polypropylene alignment tool

Since it is not machined like the other conceptions (which makes the product more expensive) and meets all the alignment tool requirements, it's the most viable conception.

4.3.6. Sole: EVA sole

It is the only element which there was no conceptions, hence the EVA has been used for this purpose for its great resistance, variety of colors and densities and its low cost.

Table 3. Main components conceptions.

Components	Conceptions		
	1	2	3
Donning	Acrylic resin donning	Modeled surlyn polypropylene donning	Modeled polypropylene donning
Body	Iron-titanium alloy connection bar	Wooden connection bar	Aluminum connection bar
Foot	Carbon fiber foot	Rubber foot	Modeled polypropylene foot
Connection element foot-body	Machined foot alignment tool	Fixation screw	-
Alignment tool (donning-body)	Round alignment tool	Machined pressure rings	Modeled polypropylene alignment tool

Another factor which contributed to the selection of conception made of modeled polypropylene, is that one can use the same technology to make various different components.

The final conception of the femoral thigh prosthesis is the following: Donning, alignment tool and foot made with modeled polypropylene, aluminum connection bar, and EVA sole.

4.4. Manufacturing process

The manufacturing process of the femoral thigh prosthesis was developed in three stages:

Tests during the conception creation: one of the criteria used to create the conception was the manufacturing process. Throughout the whole stage of creating the component conception, the manufacturing process was tested and modified in order to adapt to the conception;

Prototype Manufacturing: during the prototype manufacturing, it could be, for the first time, visualized the prosthesis manufacturing macro process. At this stage it was defined the whole process: matrix acquirement, molding order, components assembly order, finishing stage, among others.

Process Flow chart and Excel file: In order to better organize and visualize the information regarding the manufacturing process, it was developed an Excel file, a process flow chart.

Basically, the macro-process of prosthesis manufacturing was split into three distinct processes: acquiring the molding matrixes for the components; molding the components; assembly of the femoral thigh.

The Figure 1 shows the matrix, components and assembled prosthesis.

Figure 2 shows the Excel file in which there are pieces of the prosthesis manufacturing process. Its content is in English because it is the native language of Angola and in which the

4.5. Process of technology transference

The femoral thigh project was developed aiming to rehabilitate and make possible the recuperation of the working capacity of those mutilated in Angola. There is a need that these prosthesis are made in Angola, not only it needs to adapt to the anthropometry of the patient, it avoids importation expenses, furthermore it creates more job positions. It was then recognized the need to transfer the technology which was developed in the project.

For Pavit (1985), Link (1997) and Walker et al. (2003) the technology transference depends of a complex interaction network and its highly dependent on the specifications from the place where the transference happens. Historical aspects, geographic context, economics, education level and the skills of the coworkers are fundamental. It shows that we will hardly have a unique model of technology transference.

Analyzing the information and technical data, we've reached the conclusion that one of the means of transferring technology would be the creation of a CD-ROM containing all the information referring to the process of manufacturing the prosthesis.

In theses context, it was developed, in a VISUAL BASIC application, a software containing:

- Macro process: allows to identify the manufacturing of the prosthesis in three big process (Figure 3).
- Flow chart of the femoral thigh prosthesis process: the macro processes are further detailed in their respective: manufacturing processes; activities; and operations (Figure 4). The unfolding of the manufacturing process is performed from the general (macro process) to the specific (operation);
- Instructions of all the operations in the manufacturing process (Figures 4 and 5);
- Materials used in the manufacturing of the prosthesis; and
- Technical parameters of the process.

For a next stage, the continuity of the project, wishes to develop a new and better detailed version of the software in HTML, to host it on the internet.

5. Conclusion

The developed conception meets the required features of quality, production limitations, low cost and large scale production. It is important to point out that all the materials used are all recyclable and easy to separate. The data used towards calculating the final cost of the prosthesis are not shown, the results estimate a cost of US$ 2,93 considering: material; labor (direct and indirect); equipment depreciation; production volume of 129 pieces a month. The prototype and the description of the process were validated by the specialists Luciano Ascanio da Silva and Manoel Leandro da Silva (both from Rita de Cassia Orthopedic from Taubate, country side of Sao Paulo). Nonetheless, t is necessary to validate the created conception and process through the submission of theory and practice of the economical and social conditions of Angola. Some complementary studies on effort and tension on the prosthesis may be performed towards enhancing the prosthesis robustness.

Through the elaboration and detailed description of the manufacturing process, personnel training is possible in order prepare them to manufacture the prosthesis. It is important to stress that theory is not enough for such preparation. It is necessary the presence of the doctor with knowledge and practical experience in training the Angolan crew.

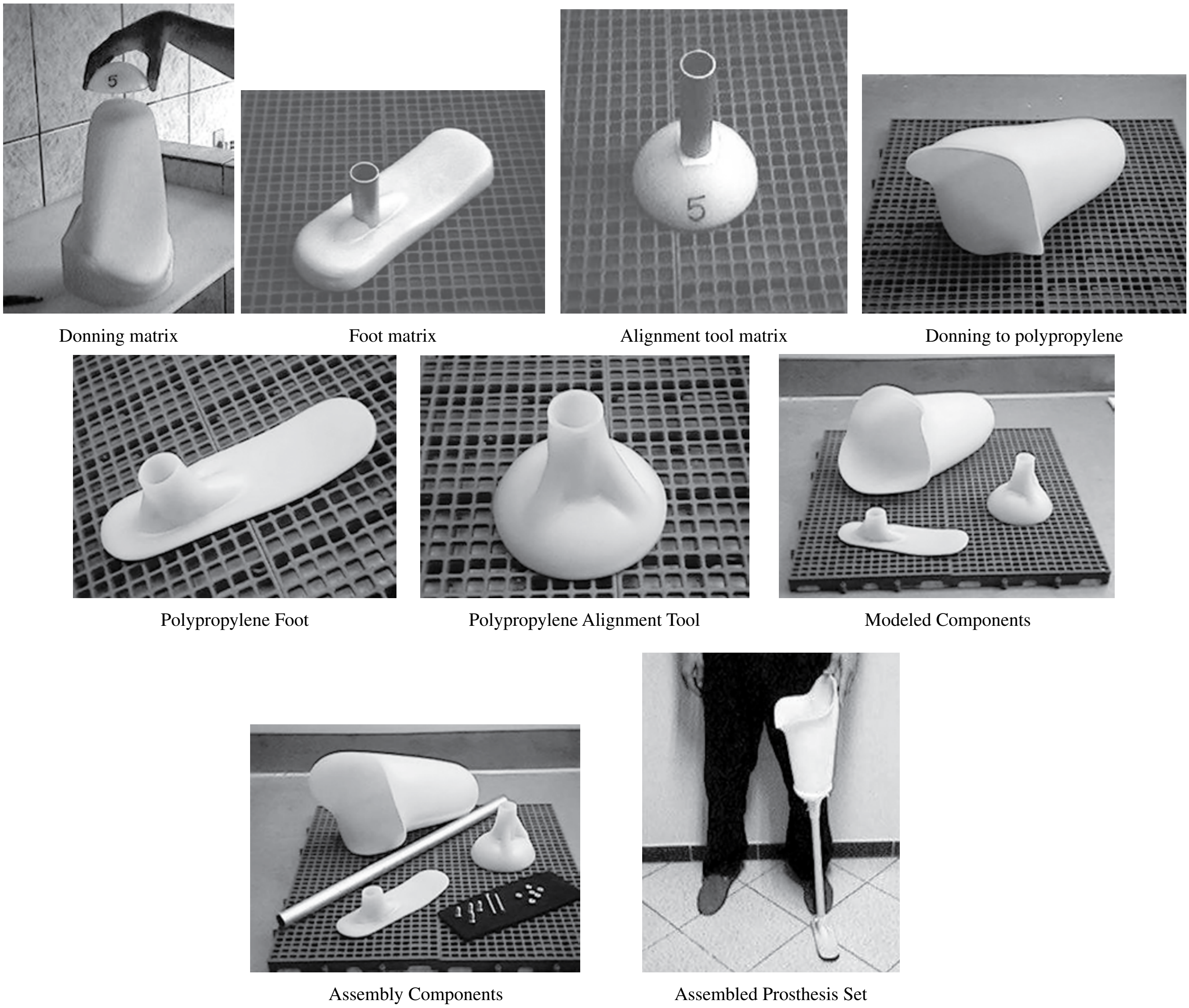

Figure 1. Matrix, components and assembled prosthesis.

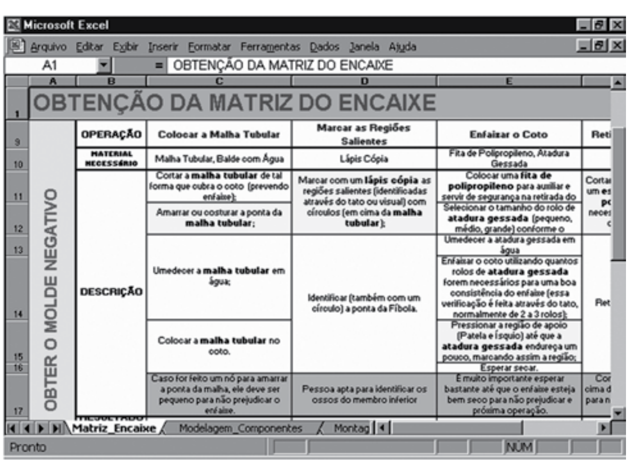

Figure 2 - Excel file with the prosthesis manufacturing process.

Figure 3. Software screen (developed in Angola native language) with the macro process of manufacturing the inferior member prosthesis.

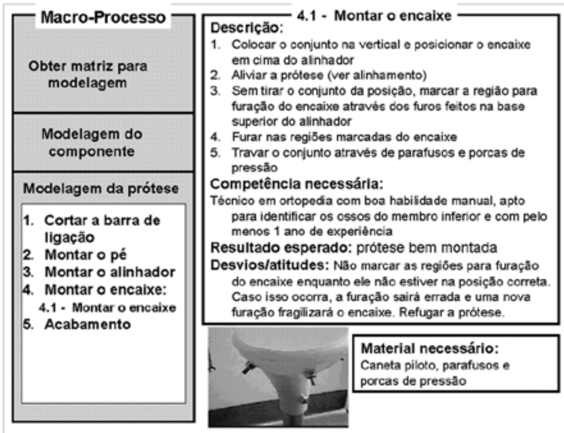

Figure 4. Screen of the software with a flow chart of the manufacturing process and screen of the software detailing the operation.

Figure 5. Screen of the software detailing the clip of the fitting manufacturing process.

The study of the need of process technology transference, resulted in a self explainable CD-ROM developed in VISUAL BASIC. Besides storing all the information and technical data inherent to the project, it can also be used as didactical material to prepare the working crew.

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