Quality of life of patients with 3D-printed arm prostheses in a rural area of Sierra Leone

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**HIGHLIGHTS**

- 3D printing may increase the accessibility of prostheses in a rural area
- A 3D printed prosthesis increases the quality of life compared to no prosthesis
- People feel included in society when using a 3D printed prosthesis instead of none
- Long term follow up is necessary to safeguard the long-term success of this project
- Costs of a 3D printed prosthesis will not be more than costs of a conventional one

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**ABSTRACT**

**Introduction:** In Sierra Leone, access to prostheses is limited due to absence of practical knowledge, materials, trained staff, and high cost. This paper investigates the impact of a 3D printed prosthesis on the health-related quality of life (HRQol) in prosthesis recipients.

**Methods:** Patients with upper extremity amputations were included in this case study from December 2018 until July 2019. Data on the HRQol was gathered until April 2020 in Masanga Hospital, central rural Sierra Leone. At two follow-up moments the HRQol was assessed by applying the standard EQ-5D-5L questionnaire. These two follow-up moments varied between one week and just over a year after receiving the prosthesis. A second patient questionnaire was used to assess prosthesis satisfaction.

**Results:** Seven patients were included. The results of the EQ-5D-5L questionnaire show no deterioration of the HRQol in any patient and the overall HRQol increased by almost 20% compared to the null measurement. One patient was lost to follow up after the first re-visit. The responses to the second questionnaire indicated that patients are satisfied with the prosthesis and use it in various situations. Patients often mentioned they feel more included in society when wearing the prosthesis. One patient says wearing the prosthesis helped in accepting the amputation. As a result, enough self-confidence was experienced without the prosthesis and the patients stopped wearing the prosthesis.

**Discussion:** The overall HRQol in patients wearing a 3D-printed prosthesis increases compared to not wearing one. Assessing the HRQol at regular intervals is important for the long-term follow-up and to safeguard sustainability and long-term success of this project. Nevertheless, defining the HRQol is challenging due to cultural differences and misunderstandings. Therefore, the use of alternative questionnaires to define the HRQol should be investigated. To improve and warrant long-term success, identifying long-term problems is important, and the second questionnaire accounts for this need.
1. Introduction

Sierra Leone is one of the poorest countries in the world, ranking 181 out of 189 countries on the UN human development index (HDI), with an average life expectancy of 54.3 years in 2019 (United Nations Development Programme, 2019). Due to a violent civil war (1991–2002) and the West African Ebola outbreak (2013–2016) the country and its healthcare system were left ravaged (Masanga; Wong et al., 2014). Even though amputations are very common, the access to prostheses is difficult due to high costs, a lack of practical knowledge, materials, and trained staff (Matter et al., 2017; Van der Stelt et al., 2020). A conventionally fabricated prosthetics costs around one fifth of the average annual income (506 USD in 2018 (The World Bank, 2019)). It is believed that 3D printing can provide a solution to this difficult access to prostheses because of a decrease in cost and easy knowledge transfer because of digital possibilities (Van der Stelt et al., 2020).

The usage and breadth of 3D printing applications is increasing in Western healthcare settings (Brouwers et al., 2018b; Choong et al., 2020; Fransen, 2015; Inge et al., 2018; Long Ng et al., 2019; Ng et al., 2018; Tack et al., 2016; Trenfield et al., 2019; Uz Leuven, 2016). Notwithstanding, in low-resource settings, the prospects of 3D printing devices in healthcare remain by-and-large unexploited (Schonwetter and Wiele Tack et al., 2016; Trencher et al., 2019). The proposal was endorsed by the Masanga Medical Research Unit Review Committee. Ethical approval for this study was subsequently granted by the Sierra Leone National Ethics committee on 6 January 2019.

2. Methods

The study took place in Masanga Hospital, Masanga, Tonkolili District, Sierra Leone. Patients were included from December 2018 until July 2019; Data was gathered until April 2020. New patients were recruited in the same way as the feasibility study previously done (Van der Stelt et al., 2020). Patients were included if they had an upper limb amputation at least four months ago. Patients were excluded when wounds on the residual limb were present or stumps were painful so that a prosthesis could not be fitted at that time. All patients received an information letter and signed an informed consent form in which they agreed to participation and therewith to the use of photos and study data in publications. Both were read out to them and translated if necessary.

2.2. Preparing a prosthesis

For all participants, individual prostheses were designed and printed. The dimensions of the residual limb and the unaffected limb used to create a prosthesis were measured with a hand-held 3D scanner (Ein-scanner Pro+; SHINING 3D Technology, Hangzhou, China; Figure 1). A patient-specific model was created using the scanned dimensions of the residual limb and the mirrored version of the contralateral arm. Any wishes concerning functionality or design were discussed with the patient before the physical design process was initiated. Any personal rehabilitation goals, for example being capable of doing laundry, were not considered. The designs were made using Meshmixer (Autodesk Meshmixer 3.5, Toronto, Canada), altered to meet the individual patients' needs and finalized using individually skin-colour adapted shades of brown paint, leather straps and/or polyether foam to prevent pressure spots. Although patients were involved in the design process, designs were kept simple to enable reproducibility. The design and manufacturing of the prosthesis have been described in detail before by Van der Stelt et al., 2020 and by Van Gaalen et al. (2021). The designs were made in close collaboration with a Dutch prosthetic specialist and a 3D specialist who were not on site but available by email and WhatsApp Messenger (WhatsApp Inc., Menlo Park, California, USA).

2.3. Data acquisition HRQoL

Patients that have received a prosthesis were actively followed-up through interviews in a face-to-face situation and, if not possible, by phone. To define the added value of a 3D printed prosthesis compared to no prosthesis, the HRQoL was determined for each patient using two types of questionnaires.

The first questionnaire was the EuroQol five-dimension, five levels (EQ-5D-5L) questionnaire to quantify the HRQoL. The EQ-5D-5L (Euro-Qol, 2019) consists of five dimensions to define an individual’s health. These dimensions are mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension has five levels: ‘no problems’, ‘slight problems’, ‘moderate problems’, ‘severe problems’, or ‘unable to do’. A score from one to five in each dimension would result in a health state score consisting of five numbers. Using a scoring algorithm, each health state can be expressed as a summary score, the EQ-5D-5L
index. This index ranges from 0 for death to 1 for full health; however, negative values as low as -0.59 are possible, known as a health state ‘worse than death’.

A value set and a norm score, which can be used to calculate the EQ-5D-5L index, are different in each country. Mainly due to different standards of living and cultural priorities. The value set determines the weight for each health state and therewith the eventual EQ-5D-5L index. Such a value set or norm score was not available for Sierra Leone. The available norm scores are found in Denmark, France, Germany, Japan, The Netherlands, Spain, Thailand, The United Kingdom, The United States, and Zimbabwe. To still be able to state a conclusion about the HRQoL, the value set of Zimbabwe was chosen to calculate the EQ-5D-5L index for each patient. Zimbabwe, ranking at the 150th place on the HDI (United Nations Development Programme, 2019), appeared to be closest to the Sierra Leonean situation in terms of culture, values and living standards and would therefore provide the most representative result. The EQ visual analogue score (EQ VAS), part of the EQ-5D-5L, was used to the Sierra Leonean situation in terms of culture, values and living standards and would therefore provide the most representative result. The EQ visual analogue score (EQ VAS), part of the EQ-5D-5L, was used to record the patient’s self-rated state of health on an analogue scale from 0 (worst imaginable health state) to 100 (best imaginable health state) (Brouwers et al., 2018a; Van Reenen and Janssen, 2015). The EQ-5D-5L questionnaires were completed at the moment of inclusion for a null measurement, and two times after receiving a prosthesis (Table 1). The mean follow-up moment 1 was at 2.2 months and the median was at 1 month. The mean follow-up moment 2 was at 8.7 months and the median was at 8 months.

A second questionnaire, a prosthesis questionnaire, was used to assess the satisfaction, the quality, the usage, the functionality of the prosthesis, and how the participants valued the prosthesis in monetary terms. This questionnaire was based on a non-validated, already existing questionnaire and can be used for further development of the prostheses. The latter since it provides us inside in the experience of the patient concerning for example the use, sustainability and comfort of the prosthesis. This questionnaire was created earlier by Gaber et al., in 2001 to assess perceived benefits of using a certain socket for upper limb prostheses and can be found in supplement file A (Gaber et al., 2001; Van der Stelt et al., 2020). The second questionnaire was completed at the same intervals as the EQ-5D-5L questionnaire but without a null measurement. The questionnaire was translated and read to the patients when appropriate. Additionally, any damage to the prosthesis and therewith the sustainability, was noted by the researchers.

3. Results

Seven patients received a prosthesis and were included in this study, of which 4 were women; the mean age was 40 years, with a standard deviation of 11.1 years (see Table 2 for demographic details). Three of the seven patients were included in a preliminary study by Van der Stelt et al., 2020 as well. Since these patients were included prior to the use of the questionnaires, a null measurement was not available and was done during the first follow-up moment. They quantified their current health state and compared this retrospectively with their health state before receiving a prosthesis. For patient 3 follow-up was done by phone due to a traveling distance of more than one day. Patient 3 was lost to follow up after the follow-up moment 1.

Figures 2–6 show four of the seven prostheses. Figure 2 shows two patients with amputations distal to the shoulder and proximal to the elbow. Figures 3 and 4 show a patient with amputated fingers and Figures 5 and 6 show a patient with an amputation just distal to the wrist.

3.1. Results of the EQ-5D-5L questionnaire

Table 3 shows the results of the EQ-5D-5L norm scores at each follow-up moment including the standard deviation. Table 4 shows the results of the EQ VAS score at each follow-up moment including the standard deviation. Figure 7 shows a graphical impression of the EQ-SD-5L norm scores per patient during follow-up; and Figure 8 shows a graphical impression of the EQ VAS scores per patient during follow-up.

The individual health states of each patient at each follow-up moment can be found in supplement file B. Patient 3 was lost to follow up after follow-up moment 1 due to a large traveling distance and a language barrier during phone conversations. In addition, no EQ VAS score was assembled during follow-up moment 1. Patient 1, 3, 4, 6 and 7 show an overall increase of the EQ-5D-5L index score throughout the follow-up moments. Patient 2 and 5 show a decrease at follow-up moment 2 in comparison with follow-up moment 1. When looking at the EQ VAS score, patients 1 and 6 show an increase at each follow-up moment, whereas patient 2 and 4 show a decrease at follow-up moment 2 in comparison with follow-up moment 1. Patient 5 shows a stable EQ VAS score and patient 7 shows a decline at follow-up moment 1, but in the end shows a higher score. Overall, the HRQoL shows an increase of 18.8% at follow-up moment 2 compared to the null measurement. The EQ VAS score shows an overall increase of 41.8% at follow-up moment 2 compared to the null measurement.

3.2. Results of the prosthesis questionnaire

In this section, an overview of the results of the prosthesis questionnaire is given. The answers provided by the patients can be found in
Supplement file B. Overall, patients indicate that they are mostly satisfied with their prosthesis, and most of them wear them for six hours per day or more. The usage varies between housework such as cooking to going out for school or work. Furthermore, most patients indicate that they feel more self-confident when wearing a prosthesis. Only patient 2 is an exception to both statements. This patient stopped wearing the prosthesis between follow-up moment 1 and 2 and indicate feeling more self-confident without a prosthesis compared to before he was wearing one.

Patient 6 and 7 developed skin problems between follow-up moment 1 and follow-up moment 2, which was mostly solved by applying foam on the pressure spots. Despite those problems, both patients were wearing their prosthesis for more hours at follow-up moment 2 than at follow-up.
moment 1. Patient 6 was wearing the prosthesis for 2–6 h per day at follow-up moment 1 and for more than six hours at follow-up moment 2. Patient 7 was wearing the prosthesis for less than two hours at follow-up moment 1 and 2–6 h at follow-up moment 2.

Reasons mentioned not to wear the prosthesis anymore were: sweaty stumps causing the prosthesis to slide off, and the absence of the desired functionality. Reasons for wearing the prosthesis and advising this type of prosthesis to others were: satisfaction about the prosthesis and its looks, a prosthesis makes them feel included in the society and community, and the prosthesis solves problems for patients because of the functionality and looks.

The prices at which patients valued the prosthesis ranged between 100,000 (10.25 USD) and 1,000,000 (102.52 USD) Leones, with a mean of approximately 570,000 (58.44 USD) Leones and a median of 500,000 (51.26 USD) Leones.

### 3.3. Sustainability

Any damage to the prostheses and therewith the sustainability of the prostheses was evaluated by the researchers. All prostheses were intact at the follow-up moments. The 3D printed parts of the prostheses were undamaged and no difference was found between painted or non-painted prostheses. Some non-3D printed attachment systems showed damage and needed replacement after one year.

### 4. Discussion

#### 4.1. EQ-5D-5L results

The mean EQ-5D-5L index shows an overall increase of HRQoL among patients receiving a prosthesis. The mean EQ VAS score also
shows an overall increase. Some aspects stand out; All patients show an increase of HRQoL at follow-up moment 1, but two patients show a decrease at follow-up moment 2. One of these two patients indicated more pain from the prosthesis during follow-up moment 2, which could be the reason for the decrease of the HRQoL. Regarding the other patient, the decrease is found in each but one domain of the EQ-5D-5L questionnaire. No specific reason was mentioned by the patient or found in the results of the generic questionnaire. Furthermore, the EQ VAS score did not decrease. Therefore, it was not possible to relate the decrease of the HRQoL to the influence of the prosthesis.

4.2. Prosthesis questionnaire results

During each of the follow-up moments, the questionnaire on usability, satisfaction and other aspects of the prostheses was completed (supplement B2). Previous results by Van der Stelt et al., 2020 showed an increase in self-confidence. This has mostly been confirmed in this research, with all-but-one patient mentioning an increase in self-confidence. Patient 2, who indicated a lower self-confidence at follow-up moment 2, stopped wearing the prosthesis because enough self-confidence was experienced without it. The patient indicated that wearing the prosthesis contributed largely to creating this self-confidence and helped with accepting the amputation.

Even though the prostheses mainly serve an aesthetic purpose, they do have some degree of functionality. For example, picking-up objects, and even cooking were mentioned as activities. Nevertheless, contrary to previous findings (Van der Stelt et al., 2020), patients were not unanimous about what was most important. One trend which can be seen in five out of seven patients (Supplement File B) is a switch in preference from aesthetics to function. At follow-up moment 1, they pointed out that aesthetics is more important than function; nevertheless, at follow-up moment 2, they either say both are of similar importance or function is more important. This could be in line with the experience of patient 2. The prosthesis helps regaining self-confidence and when regained, functionality becomes a more important aspect. Patient 5 shows a different trend. This patient preferred a more functional prosthesis at follow-up moment 1, but considered aesthetics and function to be evenly important at follow-up moment 2. Therefore, for the future of the project, possibilities of adding sustainable functionality could be considered for example by enabling movement of the wrist or thumb. Nevertheless, it is believed that functional hands consisting of multiple printed parts, which are used in some described 3D print projects in rural areas (Zaniga et al., 2015, 2016), will be too complex to use and repair in rural areas such as Masanga.

Patients 6 and 7 developed skin problems in between the follow-up moments. Both patients started wearing the prosthesis for longer periods during the day in between follow-up moments; it could be that wearing the prosthesis longer is related to the developed skin problems. Therefore, continuing follow-up is important to enhance the prostheses when necessary and prevent skin problems.

One aspect mentioned by several patients, and also a confirmation of prior research in this project (Van der Stelt et al., 2020), is that patients feel more included into society. This may help to improve their quality of life since it will enable them to participate in society again. For example, patients in this study felt confident enough to return to school, most of them to learn and one of them to teach.

Patients value a prosthesis around 570,000 Leones (58.44 USD), which is around 11.7% of the gross national income per capita in Sierra Leone in 2019 (The World Bank). This price would be out of reach for most Sierra Leoneans and maintaining a low cost will therefore be important in the continuation of the project. The prostheses created in this study have an estimated value of around 14 USD for a forearm (Van der Stelt et al., 2020). These costs are without overhead costs and time investments; however, it is not believed that the eventual costs will be more than the one fifth of the annual income which is mentioned in the introduction as the costs for a conventionally fabricated prosthesis.

4.3. Limitations

This research has some limitations. Firstly, the number of participants is limited due to the Covid-19 outbreak but inclusion was paused since the authors were eager to publish the here described results. When it comes to evaluating the EQ-5D-5L questionnaire, several aspects are worth considering. First of all, some patients were included in the project prior to the application of the questionnaires. The score at both follow-up moment 1 and the null measurement were therefore determined during follow-up moment 1. A systematic review of Scholten et al. (2017) showed that it is important to consider recall bias, which may arise in a HRQoL assessed retrospectively. Nevertheless, Lawson et al. (2020) recently showed, in a test-retest setting, that the agreement between prospective and retrospective measurement of HRQoL using the EQ-5D-5L was high at group level even with any recall bias, meaning that the EQ-5D-5L questionnaire can be used as a valid tool to estimate the baseline HRQoL. Despite the results found by Lawson et al. it is still
important to keep in mind that retrospective data gathering may be biased on individual level.

Secondly, the index scores are based on the value set found for Zimbabwe. Conclusions can be drawn on the decrease or increase of the EQ-5D-5L index. However, it is known that the HRQoL is influenced by many aspects and not only having a prosthesis (Demet et al., 2009). Therefore, the increases or decreases in HRQoL might be caused by more factors than solely the prosthesis.

Thirdly, there is a large cultural difference between Sierra Leone and the country of residence of most of the authors. These cultural differences, as shown by Levitt in 2016, may have led to difficulty in communication and therefore to filling in the EQ-5D-5L and the prosthesis questionnaire (Levitt, 2019). It was experienced that some questions were difficult to answer, mostly because questions were repeatedly misunderstood by the patients.

To overcome this limitation, a local physiotherapist was instructed to ask out the questionnaires, and contributed largely to the increased trustworthiness of the results. Nevertheless, there was still a large language barrier through the phone when talking to patient 3 and therefore, this patient was lost to follow up after follow-up moment 1. Furthermore, it was experienced that the EQ-5D-5L questionnaires could result in a lower score in other cultures than they have in this research. For example, that patients feel independent and do not use or need help in doing their usual activities, like grocery shopping or fetching water. However, it costs them double the time it did before the amputation since they are missing a part of an upper limb. This doubling of time was not reflected in the results of this study. Another example is that patients experience no anxiety or depression, whereas they do express that they feel left out by the society because of their disability, causing them to feel sad. This feeling of sadness could be described as a form of depression or anxiety in other cultures. Furthermore, mental health care is underdeveloped in Sierra Leone and most psychiatrists are foreign (Alonso et al., 2014). Therefore, Sierra Leoneans might not be familiar with the term depression or other mental health issues. Therefore, to come to a solid conclusion about the research work described here, the HRQoL increased when wearing a 3D printed prosthesis. This increase in HRQoL suggests that a 3D printed prosthesis is of added value compared to no prosthesis. This comparison for now (Van Gaalen et al., 2021). In future research, it is suggested to look into the added value of a 3D printed prosthesis compared to a conventional prosthesis.

5. Conclusion

To our knowledge, this is the first long-term follow-up study into 3D printed upper limb prostheses. Based on the results of this study, it can be concluded that the HRQoL could improve in patients when receiving an accessible low-cost 3D printed prosthesis. However, we did experience difficulties using the EQ-5D-5L in this setting and therefore advice to consider the use of another HRQoL questionnaire. Furthermore, based on the prosthesis questionnaire, self-confidence and enrolment in the society improves. Long-term follow-up is needed to prove the sustainability of the prostheses and confirm the improvement in HRQoL of patients.

Declarations

Author contribution statement

Andrea Sterkenburg and Merel van der Stelt: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper. 
A.R. Koroma and Michelle van der Pol: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data. 
Martin Grobusch and Kees Slump: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data. 
Melissa van Gaalen: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data. 
Lars Brouwers: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper. 
Thomas Maal: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

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Data included in article/supplementary material/referenced in article.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

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