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Water Jet Applicator for Interface Tissue Removal in Minimally Invasive Hip Refixation: Testing the Principle and Design of Prototype

Mechanical loosening of implants is in the majority accompanied with a periprosthetic interface membrane, which has to be removed during revision surgery. The same is true if a minimal invasive (percutaneous) refixation of a loose implant is done. We describe the requirements for a waterjet applicator for interface tissue removal for this percutaneous hip refixation technique. The technical requirements were either obtained from a literature review, a theoretical analysis, or by experimental setup. Based on the requirements, a waterjet applicator is designed which is basically a flexible tube (outer diameter 3 mm) with two channels. One channel for the water supply (diameter 0.9 mm) and one for suction to evacuate water and morcellated interface tissue from the periprosthetic cavity. The applicator has a rigid tip (length 6 mm), which directs the water flow to create two waterjets (diameter 0.2 mm), both focused into the suction channel. The functionality of this new applicator is demonstrated by testing a prototype of the applicator tip in an in vitro experimental setup. This testing has shown that the designed applicator for interface tissue removal will eliminate the risk of water pressure buildup; the ejected water was immediately evacuated from the periprosthetic cavity. Blocking of the suction opening was prevented because the jets cut through interface tissue that gets in front of the suction channel. Although further development of the water applicator is necessary, the presented design of the applicator is suitable for interface tissue removal in a minimally invasive hip refixation procedure. [DOI: 10.1115/1.4043293]

1 Introduction

A common finding in patients with mechanical hip prostheses loosening is the development of a soft-tissue membrane between the host bone and the implant, the so-called interface tissue [1,2]. Worldwide, the hip prosthesis revision rate at 10-year follow up is estimated at 12% [3] and revision rates are expected to increase in coming decades [4]. Presently, patients can only be treated by complete removal of the loosened prosthesis and interface tissue and insertion of a new prosthesis during open revision surgery. This procedure is highly demanding for the patient as well as for the surgeon. In patients with poor general health, the complication rate is high, with up to 60% complications in the American Society of Anesthesiologists 3 patient category [1]. The mortality rate after receiving revision surgery (3555 patients) within the United States Medicare Population 1998–2011 is, respectively, 1.4% and 2.1% at 3 months and 12 months after revision surgery [5]. For these patients with comorbidity, there is a need for a less invasive alternative to open revision surgery.

Therefore, a new minimally invasive hip refixation procedure is being developed. This procedure is intended to (partially) remove the periprosthetic interface tissue while the prosthesis stays in place, and to inject bone cement into the periprosthetic osteolytic areas. With the use of a finite element study, Andreykiv et al. [6] showed that cement injection after interface tissue removal can contribute to the overall implant stability. Malan et al. [7] showed that removal of this periprosthetic interface tissue facilitates a better cement distribution compared to patients without interface removal. De Poorter et al. investigated a gene therapy approach to remove the interface tissue, with promising results [8–10]. The latter is still experimental and limited to academic centers with facilities to perform gene therapy [11]. For that matter, we explored a technological approach to remove the interface tissue. This requires the development of a new surgical instrument,

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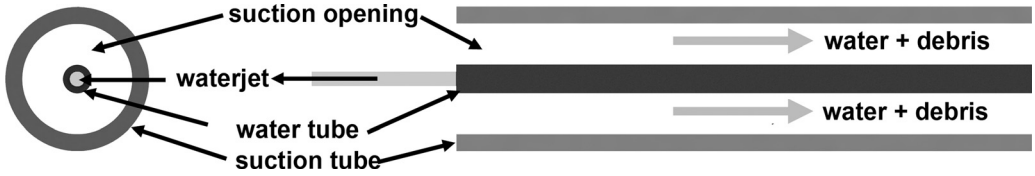

Fig. 1 Schematic overview of the waterjet applicator with integrated suction used in initial trials

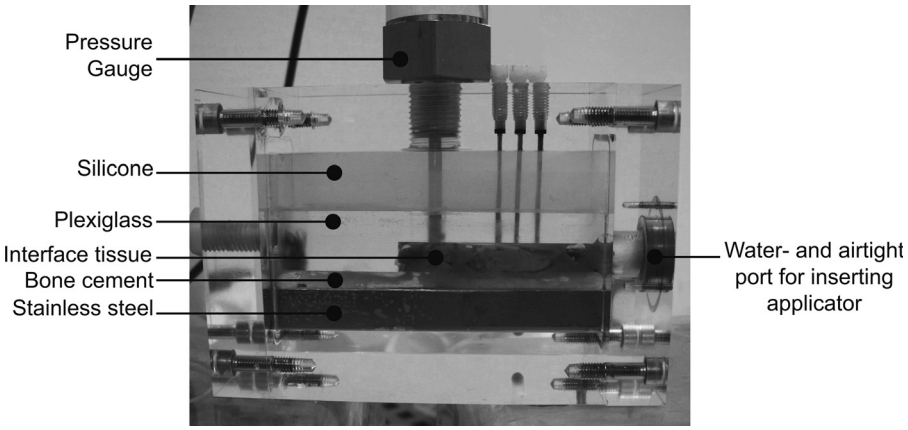

Fig. 2 Schematic overview of experimental setup for simulating interface tissue removal

which first has to gain access to the interface between bone and loosened implant (periprosthetic cavity) and second has to remove the interface tissue.

In a previous cadaveric study, we showed that a Ho:YAG laser could be used for interface-tissue removal, but the additional effect of this technique is that also thermal damage of bone might occur [12]. Therefore, the feasibility of waterjet cutting of interface tissue as an alternative removal technique was explored [13]. Cutting with a waterjet does not generate heat and can be advantageous over conventional cutting tools such as mechanical cutters, laser dissectors, or ultrasonic aspirators [14]. Tissue can be cut within small spaces (i.e., the periprosthetic cavities) with very low reaction forces (<5 N) [15]. Moreover, the cut is always sharp and clean, which has led to further exploration of waterjet technology for application in orthopedic surgery [15–18]. Finally, water (or saline for in vivo application) can be supplied via flexible tubing, which offers possibilities for minimally invasive surgical access and control of the direction of the waterjet. The study of Kraaij et al. [13] showed that it is possible to selectively cut tissues with different mechanical properties by adjusting the pressure and the diameter of the jet. This is explained by the fact that waterjet pressure required to cut interface tissue is about 1/3 of the waterjet pressure required to cut bone [13].

Besides the aforementioned advantages, there is one drawback of waterjet cutting: if the balance between water input and water output from the periprosthetic interface cavity is not maintained, a water pressure buildup can occur within the marrow cavity of a bone. It is believed that an increased pressure within the marrow cavity of a bone (intramedullary pressure) is the most important pathogenic factor for the development of embolic events [19,20]. Acute hypotension, hypoxemia, cardiac arrest, and sudden death are well-recognized complications during (cemented) total hip arthroplasty, and they have been attributed to embolization of fat and bone marrow. Initial trials of interface tissue removal with a waterjet applicator with integrated suction for removal of introduced water (Fig. 1) were performed in an experimental setup (Fig. 2) simulating the presence of periprosthetic interface tissue. Chicken liver was used as substitute for the interface tissue because it is a very soft tissue. In contrast to interface tissue, it easily falls apart in large pieces which can easily block suction openings or tubes. We therefore considered chicken liver as a worst case scenario in testing waterjet cutting of tissue in the periprosthetic interface cavity. These initial trials showed a rapid increase in simulated bone marrow cavity pressure in case the suction opening was blocked by tissue. Water was being injected under high pressure, but it could not be removed. Therefore, a waterjet applicator for interface tissue removal had to be designed that eliminates the risk of water pressure buildup. The purpose of this study is to describe the requirements for and the design of such a new applicator and to demonstrate the functionality of this new applicator using a prototype of only the applicator tip. This new applicator is specifically designed to prevent tissue blocking after the tissue has been morcellated and has to be evacuated from the target area (i.e., the periprosthetic area), taken into account the required waterjet settings to cut periprosthetic interface tissue as found by Kraaij et al. [13].

2 Design Requirements

2.1 General Requirements. General design requirements for the waterjet applicator for minimally invasive tissue removal were either obtained from literature review, determined from results from the previous work or determined by theoretical analysis. Table 1 summarizes the resulting design requirements. Per requirement, an explanation is given later about how the requirement value was determined.

During cemented total hip arthroplasty, cement is injected under pressure to achieve the recommended bone-cement interdigitation and a cement mantle of 2–5 mm in all areas [21]. A pressure of approximately 2000 mmHg (267 kPa) is assumed to be sufficient to obtain an adequate cement mantle [22,23]. Cement applicators that stop automatically at a pressure of 267 kPa were successfully tested (clinically) [24,25]. Based on the earlier studies [22–25], the increase in intramedullary pressure should stay below 267 kPa while applying the waterjet, which is comparable to the injection pressure during hip stem cementing.

Based on the results of Kraaij et al. [13], a waterjet with diameter 0.2 mm and working pressure 12 MPa or a jet with diameter 0.6 mm and working pressure of 10 MPa would be feasible for

Table 1 Overview of general design requirements/conditions

General design requirement #	Description	Value	Explanation
G.1	Increase in intramedullary pressure	$\leq$267 kPa	Schmidutz et al. [21]
G.2	Nozzle diameter	0.2 mm	Kraaij et al. [13]
G.3	Waterjet pressure	$\geq$12 MPa	Kraaij et al. [13]
G.4	Applicator diameter	$\leq$ 3 mm	Section 2.2
G.5	Applicator insertion length	$\geq$200 mm	Section 2.2

interface tissue removal. As discussed in the study of Kraaij et al. [13], the flow rate for a 0.2 mm nozzle was about eight times lower than the flow rate for the 0.6 mm nozzle. During interface issue removal, there must be a balance between water input and water output from the periprosthetic interface cavity to avoid a water pressure buildup. Therefore, a size 0.2 mm nozzle is chosen in the waterjet applicator for tissue removal. This diameter of the nozzle not only warrants that less water needs to be evacuated from the periprosthetic cavity but also warrants that in case of a disbalance between inflow and outflow (i.e., suction), the pressure buildup in the periprosthetic area will less quickly become critical with respect to bone fatigue.

2.2 Applicator Diameter and Insertion Length. In earlier studies conducted at the Leiden University Medical Center [9–11], seventeen patients received minimally invasive cement injections using vertebroplasty needles with a length of 100 mm (Biomet, Dordrecht, The Netherlands). This same type of needle will be used in the minimally invasive hip refixation procedure to introduce the waterjet applicator into the interface tissue. Because the waterjet applicator will have to bridge the length of the needle and has to move around the loose hip prosthesis, the applicator insertion length was set to be at least 200 mm: twice the length of the needle.

Pre-operative computed tomography (CT) scans of 18 loosened hip prostheses from the abovementioned 17 patients were used to estimate the maximal feasible diameter of the waterjet applicator that would be able to reach as much of the interface tissue as needed. The CT images were grouped into regions A–D, as shown in Fig. 3.

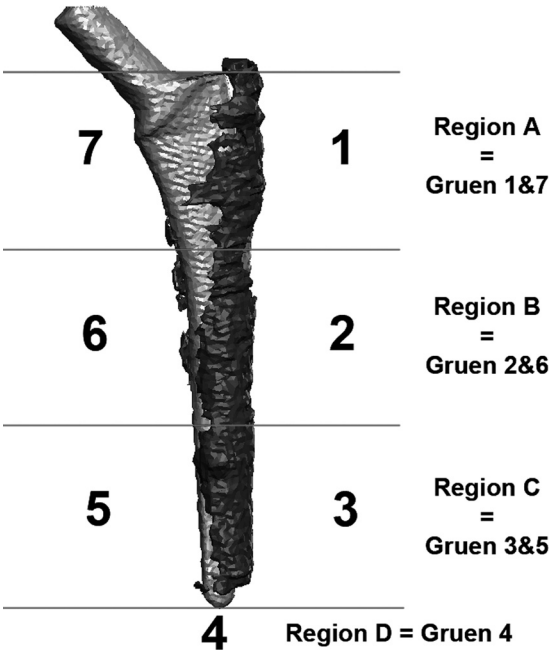

Fig. 3 A prosthesis surrounded with interface tissue, divided into the four regions A to D

To get insight in how much interface tissue should be removed at each region, six orthopedic surgeons from different hospitals in The Netherlands were asked; "How much of the interface tissue has to be removed?." The orthopedic surgeons were not restricted in any way when providing us with an answer. The majority of the surgeons answered that it is depended on the patient. They mentioned, e.g., that "the proximal part is the most important region to remove the interface tissue in order to regain stability of the implant" and "The tissue has to be removed at critical points, and enough to obtain a good refixation after the cement injection." which is in accordance with the results of the finite element study of Andreykiv et al. [6]. Andreykiv et al. conclude that cement injection into the proximal area (region A) has the highest effect on hip refixation as compared to medial (region B) and especially distal areas (regions C and D). In fact, even in case of the best possible outcome of the surgery, cement injection in region D does not have effect on hip refixation. Based on the results of the study of Andreykiv et al. [6], the waterjet applicator will be designed for interface tissue removal in region A, while taking into account the information from the orthopedic surgeons that at least 70% of the interface tissue has to be removed.

As a measure of how much interface tissue could theoretically be removed by the new waterjet applicator, the percentage of reachable area was determined for different applicator diameters (2–4 mm, interval of 0.5 mm). In the pre-operative CT images, osteolytic lesions were manually segmented by an expert user in a slice-by-slice mapping using the Medical Imaging Tool Kit (MITK 0.12.2), an interactive segmentation software tool [26]. Each segmented slice was saved as a tif file in which the interface tissue was represented by the white pixels (Fig. 4(*a*)). The imaging toolbox of MATLAB (Mathworks, Inc., Natick, MA) was used to calculate how much tissue could be reached and removed depending on which applicator diameter would be chosen. Per slice in regions A–C, each white pixel was used as the center point of a circle representing the diameter of the applicator. If the circle fitted within the boundaries of the tissue (white area), the area of the circle was subtracted from the total area representing the tissue (Figs. 4(*b*)–4(*e*)). This process was repeated for five different potential diameters of the applicator.

The fraction of the interface tissue that could be removed with an instrument of a certain diameter is defined as

$$\mathrm{FI}_R = \frac{\sum_{k=1}^{N} A_{i,k} - \sum_{k=1}^{N} A_{r,k}}{\sum_{k=1}^{N} A_{i,k}} \tag{1}$$

in which N is the number of slices in region R, $A_{i,k}$ (mm^2) is the initial area of interface tissue in a slice, and $A_{r,k}$ (mm^2) is the remaining area of interface tissue per slice that could not be reached with the instrument. An FI_R of 1 means that all the interface tissue could be removed with an applicator of the tested diameter and a ratio of 0 indicates that no tissue could be removed.

The results of the applicator diameter analysis are shown in Fig. 5. The thick horizontal line running through the entire figure indicates the removal threshold desired by the clinicians: at least

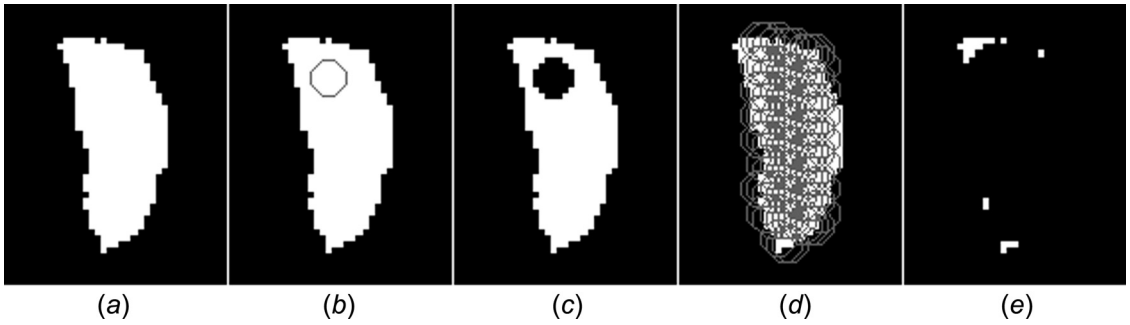

Fig. 4 Schematic overview of tissue layer thickness measurements: (*a*) original interface tissue area (white) in a slice, (*b*) when a circle as large as the instrument diameter fits within the interface tissue area, it is projected on this area, (*c*) the area of the circle is subtracted from total tissue area, (*d*) whole interface tissue area is scanned, (*e*) remaining interface tissue (shown in white) that cannot be reached with the instrument of the diameter shown in "b"

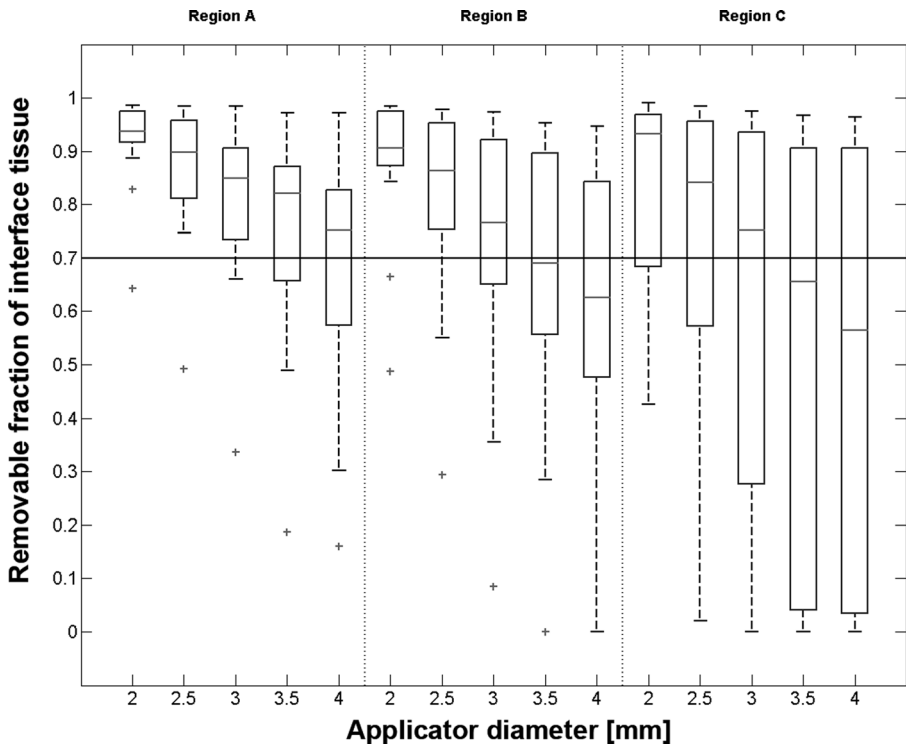

Fig. 5 Boxplot of removable fraction of interface tissue around 18 loose hip prostheses, accessible for applicator with different diameters, determined per region. Outliers are indicated with a+, the thick horizontal line indicates the 70% threshold of interface tissue to be removed.

70% of the interface tissue has to be removed, where the proximal part (region A) is the most important region. Based on the results, we have set the applicator diameter to 3 mm. The removal threshold is met in at least 75% of the cases, which we considered to be a good starting point for the first applicator prototype. In order to meet the removal threshold, the applicator should have a 2.5 mm diameter. However, setting the diameter to 2.5 mm does increase the design challenge. Section 6 discusses what is needed to decrease the applicator diameter.

3 Applicator Design and Working Principle

Based on the requirements given in Table 1, an instrument was designed. A schematic overview of this design is given in Fig. 6. The instrument basically is a (suction) tube with two channels, one for the pressurized water supply and one for suction to

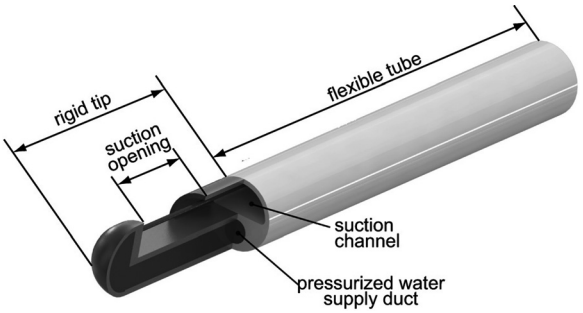

Fig. 6 Design of new waterjet applicator that prevents tissue blocking. The tip is partially represented as a cross section to show the working principle.

Table 2 Overview of dimensional design requirements

Dimensional design requirement #	Description	Value	Explanation
D.1	Dimensions of pressurized water supply duct		Section 3.1
	• Inner diameter • Minimum wall thickness	0.9 mm 0.3 mm	
D.2	Angle of instrument insertion		Section 3.2
D.3	Rigid tip length	6 mm	Section 3.2
D.4	Number of nozzles	2	Section 3.3 (Theoretical) Section 4.1 (Experimental method) Section 5.1 (Experimental results)
D.5	Suction opening	1.5 mm (type 3)	Section 3.3 (Theoretical) Section 4.1 (Experimental method) Section 5.1 (Experimental results)

evacuate water and interface tissue from the periprosthetic cavity. In the tip of the applicator, the water flow direction is redirected to create waterjets that are aimed into the suction channel such a way that the waterjets remain within the outer contour of the tube. Vacuum is applied to the suction channel, pulling the interface tissue into the suction opening, causing the tissue to get into the waterjets and be morcellated. The water is immediately evacuated from the periprosthetic cavity as the waterjets are aimed into the suction channel. Additionally, blocking of the suction opening will be prevented because the jets will cut through interface tissue that gets in front of the suction channel. The dimensional design requirements for the designed applicator as determined earlier are summarized in Table 2.

First explanation of the values that are theoretically determined, followed by experiments to determine #D.2 and #D.3 and results of the prototype tests.

For pragmatic reasons, a bench top prototype of the applicator tip was made from stainless steel (tip must be rigid) and it was manufactured mostly according to the requirements given in Tables 1 and 2, as the purpose was to demonstrate the functionality (working principle) of this new applicator. The nozzle diameter had to be enlarged to 0.3 mm and tip length was 8 mm for reasons of manufacturability. The bench top prototype applicator tip shown in Fig. 7 is an assembly of three parts: a body, a cover, the cover soldered inside the body, and a capillary tube (inner diameter 0.9 mm) glued into the body. The body contains a water supply duct, a suction channel, and two waterjet orifices of 0.3 mm diameter that were machined by spark eroding. The capillary tube is used to connect the applicator tip to the high pressure source adaptor. Again, this was done this way to be able to test the working principle. Before the applicator can be used in clinical practice, some iterations regarding manufacturability are necessary. In Sec. 6, this will be discussed in more detail.

3.1 Water Supply Duct Dimensions. For the dimensions of the pressurized water supply duct, some restrictions had to be taken into account:

- The outer diameter is limited because of the applicator diameter and because a part of the cross-sectional area of the instrument is used for suction.
- The inner diameter of the water supply duct must be as large as possible to minimize the pressure drop.
- The wall of the pressurized water supply duct must be thick enough to withstand the waterjet pressure.

The required wall thickness for a round duct can be determined using Barlow's equation

$$P = \frac{2St}{d_o} \tag{2}$$

where P is the burst pressure (MPa), S is the wall material's allowable stress (N/mm^2), t is wall thickness (mm), and d_o is the outside duct diameter (mm).

Rewriting Eq. (2) to solve for t gives

$$t = \frac{Pd_0}{2S} \tag{3}$$

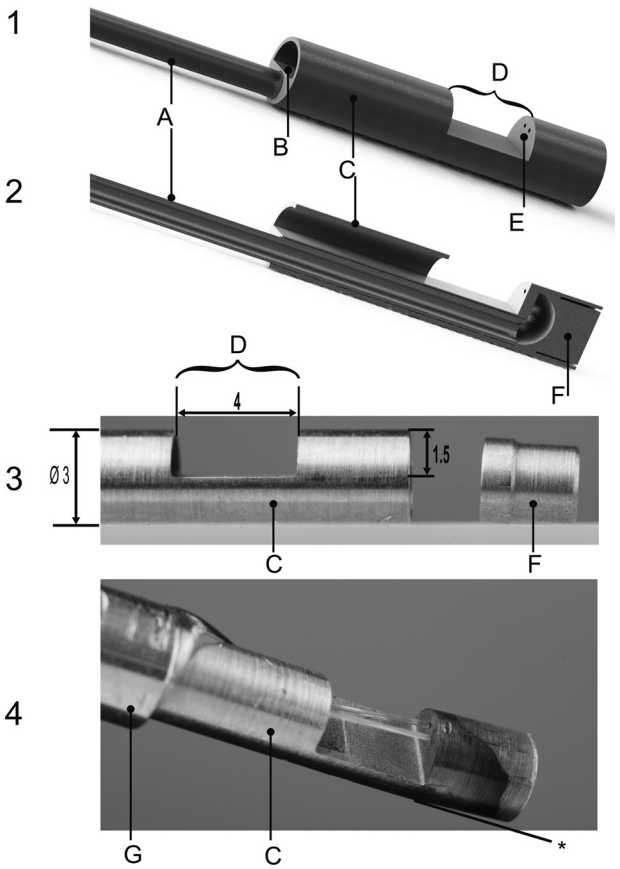

Fig. 7 Bench top prototype applicator tip with two waterjets: (1) 3D rendering, (2) 3D rendering of longitudinal cross section, (3) photograph of separate parts, and (4) photograph of assembled prototype in action. (A) capillary tube, (B) suction channel, (C) body, (D) suction opening, (E) orifices for waterjet, (F) cover, and (G) connection to silicone suction tube. *Prototype slightly bent to get waterjets aimed into suction channel. Dimensions in millimeter.

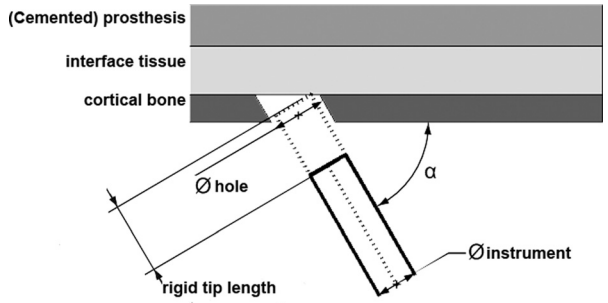

Fig. 8 Graphical representation of the simulation used to determine the maximal allowable rigid tip length

For safety, the burst pressure of the applicator duct was set at 24 MPa, which means it should be able to withstand twice the waterjet pressure required for cutting interface tissue. The water supply duct must be dimensioned such that the applicator can withstand the required waterjet pressure, the corresponding pressure drop is acceptable, while the suction channel must be as large as possible to facilitate easy removal of ejected water and morcellated interface tissue. Compared to the suction part of the applicator, the cutting water output needs much higher pressures. Consequently, the inner duct diameter is smaller. However, the water supply duct will require a thicker wall to withstand the waterjet pressure. Therefore, as a starting point, it was decided to use half of the applicator cross section for the water supply duct and the other half for the suction channel. Because the inner diameter of the water supply duct should be as large as possible to minimize the pressure drop, the outer diameter d_0 was set to the maximum available space of half the instrument body diameter: 1.5 mm.

In 2008, Kroh et al. [27] developed a flexible Pebax (polymer in the nylon family) catheter with four microdrilled holes (diameter 0.2 mm in row on one side, near the tip of the catheter) for delivery of a waterjet. Based on this study, Pebax 7233SA01 with a material strength of 56 N/mm^2 was chosen as a material for the instrument body.

Using Eq. (3) and the information provided earlier, the resulting wall thickness of the water supply duct is 0.32 mm. As the wall thickness and the outer diameter of the water supply duct are known, the inner diameter d_i is also known ($d_i = d_o - 2t$). The inner diameter d_i of the water supply duct is 0.86 mm.

3.2 Rigid Tip Length. The waterjet applicator will have to be inserted into the interface area between bone and loose prosthesis and will have to remove the interface tissue, while the applicator is inserted between (cemented) prosthesis and cortical bone. As the applicator will be used minimal invasively, access to the interface tissue is gained through a small hole in the bone and the applicator must be navigated from this entrance to the area where interface tissue must be removed. In order to facilitate this insertion and navigation, the instrument must be flexible. However, the tip of the applicator must be rigid to assure that the waterjets are continuously aimed in the suction channel in any position of the instrument, with a minimum length to accommodate the suction area and allow generation of the required waterjets. However, the allowable rigid tip length is limited, taking into account that the applicator needs to be inserted into the area between bone and prosthesis, otherwise the applicator will jam during insertion.

Table 3 Parameters used for simulation instrument insertion

Parameter	Value
Instrument diameter	3.0 mm
Minimum bending radius of the applicator tip	6.0 mm
Interface issue layer thickness	4.0 mm
Cortical bone thickness	2.0 mm
Diameter of cortical bone hole	4.0 mm
Insertion angle α	30–90 deg

Table 4 Maximum allowable length of the rigid tip without jamming during insertion versus angle of applicator insertion

Insertion angle	30	40	50	60	70	80	90
Maximum rigid tip length (mm)	6.0	5.0	4.0	4.0	3.0	3.0	3.0

The maximum length of the rigid tip (i.e., allowing proper insertion via a needle or trocar into the interface tissue layer) was determined by a simulation study using MATLAB (Mathworks, Inc.). In this simulation, an applicator is inserted through a predrilled hole in the cortical bone into an area representing interface tissue between the cortical bone and the implant (Figs. 8 and 9). Fixed parameters used in this simulation are given in Table 3.

For varying angles of insertion, the corresponding maximum allowable rigid tip length was calculated. With decreasing angle of insertion, the volume of bone that will be drilled away increases. In discussion with orthopedic surgeons, the minimum angle of insertion was set to 30 deg, as with smaller insertion angles the bone and surrounding tissues (e.g., muscles and skin) are likely to be damaged (e.g., more likelihood of bleeding) due to a larger insertion trajectory and a much longer needle is needed (depended also on the body mass index, BMI of the patient), which creates potential problems for needle bending or even breakage. The resulting maximal allowable tip lengths are given in Table 4.

Based on the simulation results, the rigid tip length was set to 6 mm. This tip length is deemed to be sufficient to accommodate the suction area and allow generation of the required waterjets, while keeping it possible to insert the applicator without jamming and at an acceptable insertion angle into the interface tissue.

3.3 Number of Jets and Size of Suction Opening. As is explained in Sec. 3.1, the dimensions of the pressurized water supply duct are restricted, and therefore, the number of jets that can be used in the applicator is limited. With increasing number of

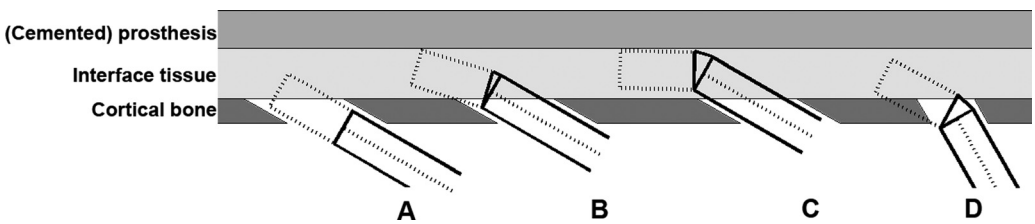

Fig. 9 Example of simulation of instrument with 6 mm rigid tip length: (A) start of instrument insertion, angle = 30 deg, (B) critical point of instrument insertion: rigid tip just fits between prosthesis and cortical bone, angle = 30 deg, (C) successful instrument insertion, angle = 30 deg, and (D) failed instrument insertion due to collision of the rigid tip with the cortical bone, angle = 60 deg

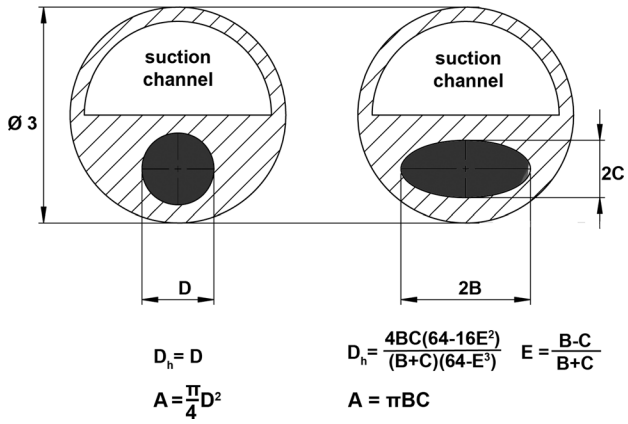

Fig. 10 Cross section of the applicator with round and elliptical shape of water supply duct. The equations are used to calculate hydraulic diameter D_h and cross-sectional area A of the water duct.

nozzles, the amount of water having to flow through the duct increases, and so does the pressure drop over the duct. The pressure drop was calculated using the Darcy–Weisbach equation [28]

$$\Delta p = f_d \frac{L}{D_h} \frac{\rho v_{\text{duct}}{}^2}{2} \tag{4}$$

where f_d is the dimensionless coefficient called the Darcy friction factor, which can be determined from the Moody diagram or by solving the modified Colebrook equation [28]; L (m) is the length of the water supply channel; D_h (m) is the hydraulic diameter of the water supply channel (Fig. 10 shows how D_H is calculated for different shapes of a water duct); v_{duct} (m/s) is the average velocity of fluid flow in a duct; and ρ (kg/m^3) the density of the fluid.

Using the principle of mass conservation, the average velocity of fluid flow v_{duct} (m/s) through a duct is calculated from the mass flow rate $\dot{m}_{\text{duct}}$ (kg/s) by

$$v_{\text{duct}} = \frac{\dot{m}_{\text{duct}}}{A_{\text{duct}}\rho} \tag{5}$$

where A_{duct} is the cross-sectional area of the water duct in the instrument (m^2) and ρ the density of water (kg/m^3).

The mass flow rate of the duct should supply the mass flow rate $\dot{m}_{\text{jets}}$ (kg/s) of all waterjets combined and is given by

$$\dot{m}_{\text{duct}} = \dot{m}_{\text{jets}} = n A_{\text{jet}} v_{\text{jet}} \rho \tag{6}$$

where n is the number of jets (-), A_{jet} is the cross-sectional area of each waterjet (m^2), v_{jet} the waterjet velocity (m/s), and ρ the density of water (kg/m^3).

The waterjet velocity can be calculated using Bernoulli's equation. Rewriting Bernoulli's equation with boundary conditions $P_1 = P_{\text{jet}}$, $P_2 = P_{\text{atmospheric}}$ (because jet in open air), $P_1 \gg P_2$, $h_1 = h_2$ and $v_2 = v_{\text{jet}}$ gives

$$v_{\text{jet}}^2 = v_1^2 + \frac{2P_{\text{jet}}}{\rho} \tag{7}$$

Using the principle of mass conservation, v_1 can be written as

$$v_1 = \frac{A_2^2}{A_1^2} v_{\text{jet}}{}^2 \tag{8}$$

Generally, the nozzle A_2 is much smaller than the duct area A_1, so the ratio A_2^2/A_1^2 is negligible, and thus, the waterjet velocity is given by

$$v_{\text{jet}} = \sqrt{\frac{2P_{\text{jet}}}{\rho}} \tag{9}$$

Substituting Eq. (9) into Eq. (6), calculating the cross-sectional area of the waterjet, assuming all jets have equal diameters, and rewriting gives

$$\dot{m}_{\text{duct}} = n \frac{\pi}{4} D_{\text{nozzle}}^2 \sqrt{2P_{\text{jet}}\rho} \tag{10}$$

And Eq. (5) can be written as

$$v_{\text{duct}} = \frac{n \frac{\pi}{4} D_{\text{nozzle}}^2 \sqrt{2P_{\text{jet}}\rho}}{A_{\text{duct}}\rho} \tag{11}$$

Combining Eqs. (4) and (11) gives

$$\Delta p = f_d \frac{L}{D_h} \frac{\rho}{2} \left[\frac{n \frac{\pi}{4} D_{\text{nozzle}}^2 \sqrt{2P_{\text{jet}}\rho}}{A_{\text{duct}}\rho} \right]^2 \tag{12}$$

Inserting the values from Table 1 in Eq. (12), calculating D_h and A_{duct} with the equations from Fig. 10, and varying the number of nozzles between one and four gives the pressure drops listed in Table 5.

The results do show that an elliptical duct shape is advantageous compared to a round duct; however, because of manufacturability, it was chosen to use a round water duct shape in the first prototype design.

Sections 4.1 and 4.2 show how these results were used to design the first prototype.

4 Experimental Methods

4.1 Determining Optimal Number of Jets and Suction Opening Dimensions. Before the applicator was designed as described in Sec. 3, a pilot experiment regarding waterjet cutting integrated into a suction tube was performed to determine the

Table 5 Overview of theoretical pressure losses over round and elliptical ducts and four different numbers of nozzles

D_{nozzle} (mm)	L (mm)	Waterjet pressure (MPa)	Duct shape (-)	Dimensions (mm)	Number of nozzles (-)	Δp (MPa)	% loss of working pressure (%)
0.2	200 mm	12	Round	$d_{\text{duct}} = 0.86$	1	0.30	2.5
					2	1.0	8.3
					3	2.2	18.3
					4	3.8	32
			Elliptical	$B = 0.45$ $C = 0.80$	1	0.065	0.54
					2	0.22	0.22
					3	0.46	0.46
					4	0.78	0.78

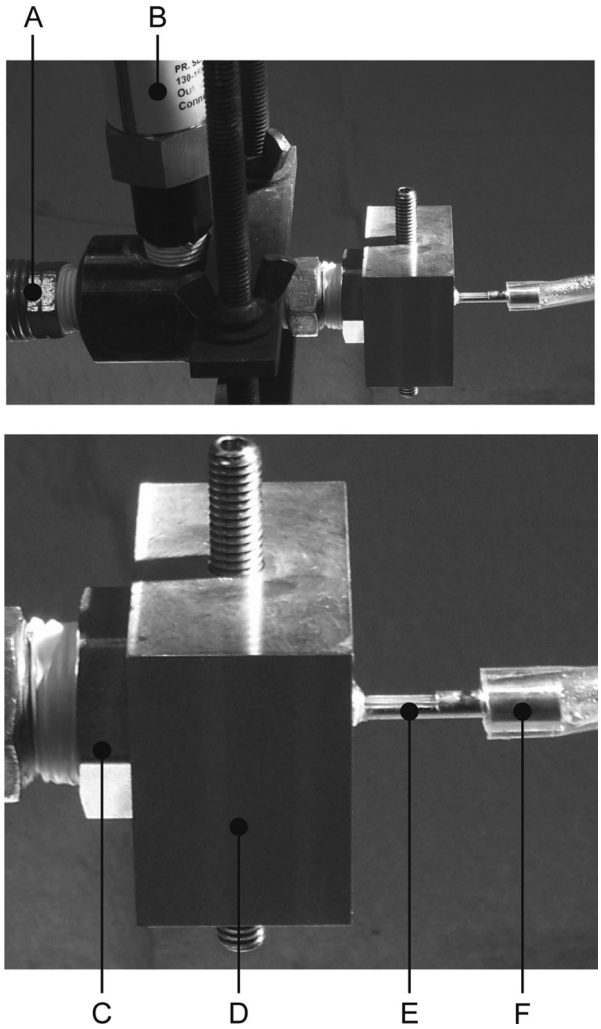

Fig. 11 At the top, an overview of the experimental setup used in the pilot experiment to determine the optimal number of nozzles and size of the suction opening. At the bottom, the applicator enlarged: (A) hose from high pressure pump, (B) pressure gage measuring waterjet pressure, (C) replaceable blind stop, (D) connector to align suction tube (opening) with the waterjet(s), (E) replaceable tube with different sized suction openings, and (F) suction hose.

actual number of waterjets and the size of the suction opening to be implemented in the prototype. The combination of the number of waterjets and the suction opening size must enable both tissue morcellation and removal. If for example just one waterjet is used, the tissue might only be cleaved instead of morcellated into pieces small enough to be evacuated through the suction channel. And if the suction opening would be too small, tissue might not flow into the suction channel. On the other hand, if the suction opening is too large, the suction channel could get obstructed because of (too) large tissue debris.

The experimental setup used for this pilot experiment is shown in Fig. 11. A high pressure cleaner (Nilfisk P 160.2, Nilfisk-Alto B.V., Almere, The Netherlands) was used as the water pressure source. The water flow through the nozzle was controlled by means of a needle valve (Nilfisk-Alto B.V.). By changing the flow, the resulting waterjet pressure was regulated. The waterjet pressure was measured in the water supply duct just before the nozzle at a sample frequency of 50 Hz using a gage pressure transducer (FPDMP333, 0–16 MPa, Altheris BV, The Hague, The Netherlands) and a data acquisition device from National Instruments (USB-6008, National Instrument, Inc., Austin, TX). The suction tube was connected to a medical suction jar, which in turn was connected to a medical aspirator (vacuum pump), set at suction level of 80 kPa. This way constant suction was applied while waterjet was active. With this experimental setup, different combinations of suction opening sizes and numbers of jets with Ø0.2 mm were tested. Each type of suction opening was tested in combination with one, two, or three nozzles. An overview of the tested combinations is given in Table 6. For this experiment, steak was used as an alternative for interface tissue first because steak is a tough tissue, thus in comparison to chicken liver it is more difficult to cut, which is in this experiment considered to be a worst case test.

Based on the data in Table 5, the maximum number of nozzles was set to three. For four nozzles, the pressure drop would become too large. Each combination shown in Table 6 was tested ten times. For each test, the removal rate of interface tissue (g/min) was determined in order to compare the effectivity of each configuration.

4.2 Applicator Prototype Test. The prototype applicator tip was connected to the same pressure source as used in Sec. 4.1 and pressure was controlled and measured in the same way as in the previous experiment. The applicator tip was placed inside an air- and water-tight plexiglass chamber. This chamber was used to simulate a tissue layer (thickness 4 mm) between prosthesis and bone. A pressure gage (FPDMK 351, 0-0.06 MPa, Altheris BV) was connected to the cavity in which tissue was placed to measure any potential pressure rise (equivalence of intramedullary pressure) during tissue removal, see Fig. 13. The suction tube was via a suction cup connected to a suction pump, which was set at 80 kPa (vacuum).

In this experiment, again chicken liver was used to represent interface tissue as we considered chicken liver as a worst case scenario in testing the applicator because it can easily block the suction opening. Before each trial, 10–12 g chicken liver was weighed using a scale (EMB 220-1, Kern & Sohn GmbH, Balingen, Germany) and placed in the chamber. The high pressure cleaner and suction pump were activated, while the applicator tip was stationary. The tissue was guided manually to the applicator tip with a pusher inserted through a water- and air-tight insertion port until all tissue was removed. The time required to remove all tissue was measured to calculate the removal rate (g/min). This was repeated ten times.

5 Results

5.1 Determination of Number of Waterjets and Suction Opening Dimensions. The removal rates found in the experiment to determine optimal number of waterjets and suction opening dimensions are provided in Fig. 14 (i.e., increasing sizes of

Table 6 Overview of settings used in the pilot experiment with waterjet cutting integrated in the suction tube

Waterjet pressure (MPa)	Suction pressure (kPa)	Tissue used	Number of jets	Suction opening types tested[a]
12	80	Steak	1	1, 2, and 3
			2	1, 2, and 3
			3	1, 2, and 3

[a]Figure 12 gives an overview of the suction opening types.

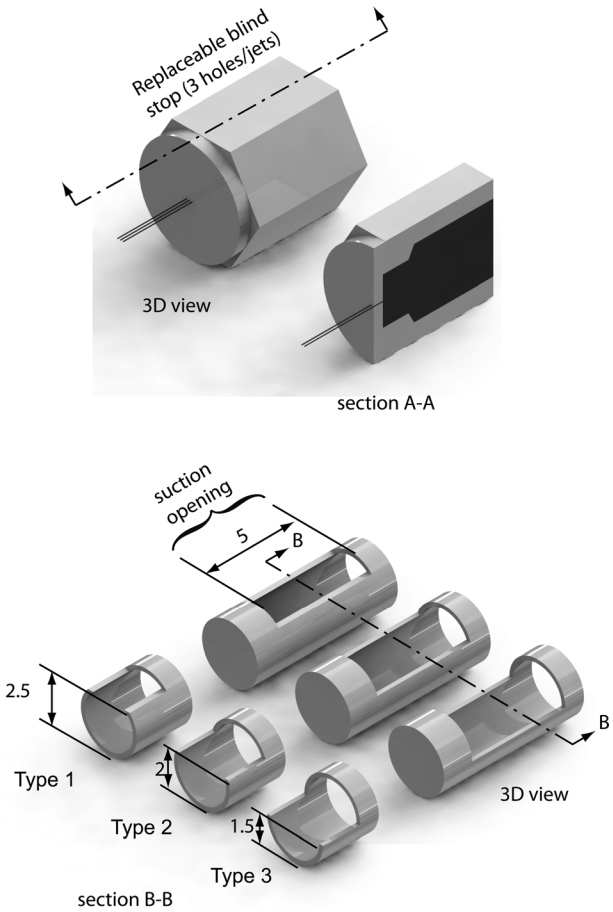

Fig. 12 At the top, a 3D and a sectional view (A-A) of the replaceable blind stop (part C, Fig. 11). Three blind stops were used with, respectively, 1, 2, or 3 holes (Ø0.2 mm each). At the bottom, a 3D and a sectional view (B-B) of the replaceable tube with different suction opening sizes (part E, Fig. 11). Both parts were used in the pilot experiment with waterjet cutting integrated in the suction tube. Dimensions are in millimeter.

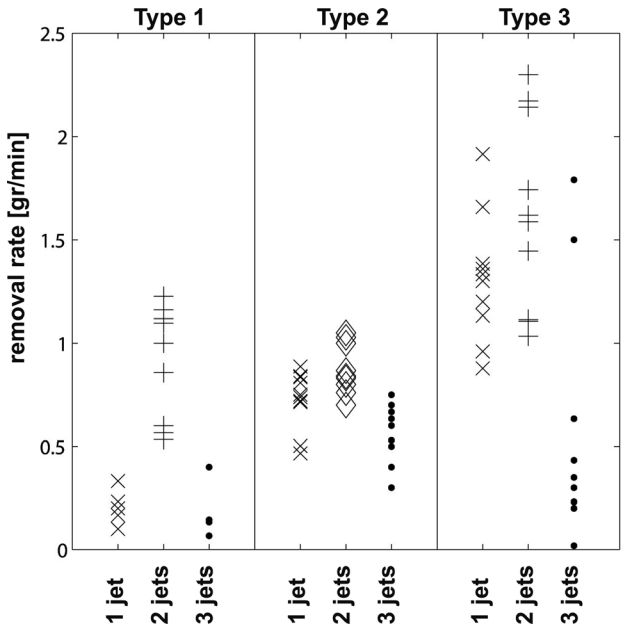

Fig. 14 Removal rates during waterjet cutting within the contours of a suction tube with different combinations of types of suction openings (varying in size and shape) and number of waterjets

suction openings and increasing the tissue removal rate). Furthermore, using two waterjets consistently resulted in the highest removal rates. Using a single jet resulted only in "slicing" the tissue, which requires continuous movement of tissue relative to the applicator in order to get tissue morcellated. Using three jets resulted in the distance between the jets getting too small, blocking the tissue from passing the jets. Furthermore, the amount of water ejected by the jets increased by 50% when using three jets instead of two jets at the same pressure. Furthermore, all the extra "inlet" water has to be evacuated through the suction channel. While performing the tests, it was noticed that as long as the waterjet is active, tissue is removed irrespective of whether the active suction was switched on or not. Based on the outcomes of the pilot experiment, it was decided to use two waterjets and a

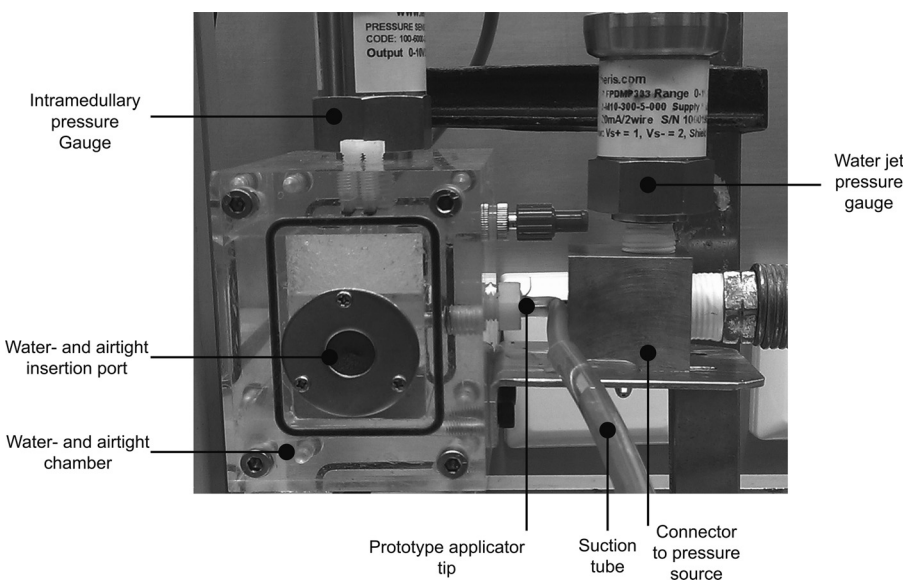

Fig. 13 Experimental setup used for prototype testing

suction opening of "type 3" in the design of the applicator for minimally invasive interface tissue removal.

5.2 Results of Applicator Prototype Testing. The prototype applicator was able to morcellate and remove tissue from a cavity in an air- and water-tight chamber. The tissue removal rate varied between 1.3 g/min and 6.8 g/min (average 3.4 g/min). No increase in intramedullary pressure was measured, except for one test. In this test, an increase of 10 kPa was measured, which is far below the maximum allowed pressure rise of 267 kPa.

As was seen during the experiment "determination of number of waterjets and suction opening dimensions" it was noticed that, even when the suction pump was not activated, the ejected water was removed from the cavity. This can be explained by the Venturi effect: due to the velocity of the waterjets along the suction opening (constricted section), the velocity of surrounding water or air increases, which results in pressure reduction in close proximity of the suction opening.

6 Discussion and Conclusion

The goal of this study was to design a waterjet applicator for interface tissue removal that eliminates the risk of water pressure buildup. For this purpose, a new applicator was specifically designed to not only morcellate interface tissue but also prevent (morcellated) tissue blocking at the suction opening. The applicator is designed such a way that it acts sideways: waterjets are integrated into the suction tube and are aimed into the suction channel passing a suction opening in the side of the suction tube. The applied waterjet pressure of 12 MPa is sufficient high to cut interface tissue but not to cut bone or bone cement [13]. As the waterjets stay within the contours of the instrument, it acts like a shaver and it is not possible to cut through (healthy) tissue.

A bench top prototype was tested. The tissue removal rate varied between 1.3 g/min and 6.8 g/min (average 3.4 g/min). Prior to using waterjets for minimally invasive interface tissue removal, HO:YAG laser and coblation were evaluated by Kraaij et al. [12]. Removal rates found were on average 0.25 g/min (Ho:YAG laser) and 0.09 g/min (coblation). Next to the advantage of no heat generation, waterjet cutting is also in advantage regarding removal rate.

Despite the fact that this prototype has waterjets of 0.3 mm instead of 0.2 mm, the prototype applicator removed interface tissue without causing any water pressure buildup. By using 0.2 mm instead of 0.3 mm diameter waterjets, the mass flow could be further reduced by half, thus requiring less water to be removed from the periprosthetic cavity. The latter also reduces the likelihood of pressure buildup. Important to realize here is that we tested the applicator tip only. If our prototype is translated to a medical device, suction tube length will increase with respect to our prototype. As the suction tube will be longer, the morcellated tissue might build up in the suction tube further away from the applicator tip. Testing has to be done to identify if this will happen. However, we do expect the combination of number of jets and suction opening size as determined in Sec. 5.1 will prevent large tissue debris flowing into the suction tube.

Before this waterjet applicator can be applied for periprosthetic interface tissue removal in a minimally invasive hip refixation procedure, further research is necessary. Access to the periprosthetic interface tissue has to be gained through a small hole in the skin and bone after which the applicator must be navigated from the bone entrance to the area where interface tissue must be removed. In order to facilitate this waterjet applicator insertion and navigation in the periprosthetic space or cavity, the instrument body must be flexible, while the tip needs to be rigid to assure a proper functioning of the applicator. A next prototype should consist of fewer parts, e.g., an instrument body and a tip. It has to be investigated how the tip can be connected to the body. And for navigation purposes, steerability of the tip must be integrated in the instrument body.

In a medical device, we consider the instrument body to be made from Pebax, as mentioned in Sec. 3.1. Pebax tubing is manufactured by extrusion, allowing to manufacture multilumen tubing, reducing the number of parts compared to our prototype. Furthermore, it makes it possible to integrate channels for tip steering purposes and to make use of an elliptical shaped duct for water supply. An elliptical shaped duct is advantageous compared to a round duct (Table 5) regarding pressure losses. This allows the use of a downsized water supply duct, which can possibly reduce the applicator diameter from 3 mm to 2.5 mm. If the diameter is decreased to 2.5 mm, the applicator can reach interface tissue in narrower cavities (Fig. 5), and subsequently, the removal threshold will be met.

In this study, only the rigid applicator tip was prototyped from stainless steel. A rigid tip can also be obtained by using Pebax, however, it has to be reinforced to obtain the required stiffness. This can be obtained by example applying an exoskeleton or braided Pebax tubing. If both tip and instrument body are made from Pebax, it will make it easier to connect the tip to the body. As Pebax is a thermoplast, hot melting can possibly be used to connect the parts.

In a next prototype, the alignment and the coherency of the waterjets must be improved. The waterjets must be perfectly aligned with respect to the suction opening, which was not the case in our prototype. The waterjets bounced against the body of the suction channel, resulting in reduced prototype performance regarding removal of water from the cavity. For this prototype, this was solved by slightly bending the end of the applicator, see Fig. 7. The coherency of the waterjets should be improved in order to reduce water mist generated by the waterjets and to prevent reduction in cutting efficiency. If for example, the orifice is oval shaped, this will affect the waterjet coherency. As the cutting efficiency of a waterjet diminishes with decreasing coherency, it is important to machine orifices properly. As the prototype was made from stainless steel, spark eroding was used to create the orifices. Laser drilling holes with very small diameter and high accuracy can be obtained. This allows to create orifices of 0.2 mm. When Pebax is used, it should be investigated if orifices of 0.2 mm can be produced resulting in aligned water jets with desired coherency.

In conclusion, the designed waterjet applicator for periprosthetic interface tissue removal will eliminate the risk of water pressure buildup during surgery. The ejected water is evacuated from the periprosthetic cavity immediately after having cut through the interface tissue to be removed. Blocking of the suction opening is prevented because the two jets cut through any interface tissue in front of the suction channel. Although further development of the waterjet applicator is necessary, it is believed that the presented design of the waterjet applicator is suitable for interface tissue removal in minimally invasive hip refixation procedures.

References

[1] Strehle, J., DelNotaro, C., Orler, R., and Isler, B., 2000, "The Outcome of Revision Hip Arthroplasty in Patients Older Than Age 80 Years—Complications and Social Outcome of Different Risk Groups," J. Arthroplasty, **15**(6), pp. 690–697.

[2] Sundfeldt, M., Carlsson, L., Johansson, C., Johansson, C., Thomsen, P., Thomsen, P., and Gretzer, C., 2006, "Aseptic Loosening, Not Only a Question of Wear: A Review of Different Theories," Acta Orthop., **77**(2), pp. 177–197.

[3] Labek, G., Thaler, M., Janda, W., Agreiter, M., and Stockl, B., 2011, "Revision Rates After Total Joint Replacement: Cumulative Results From Worldwide Joint Register Datasets," J. Bone Jt. Surg., **93**, pp. 293–297.

[4] Kurtz, S., Ong, K., Lau, E., Mowat, F., and Halpern, M., 2007, "Projections of Primary and Revision Hip and Knee Arthroplasty in the United States From 2005 to 2030," J. Bone Jt. Surg. Am., **89A**(4), pp. 780–785.

[5] Badarudeen, S., Shu, A. C., Ong, K. L., Baykal, D., Lau, E., and Malkani, A. L., 2017, "Complications After Revision Total Hip Arthroplasty in the Medicare Population," J. Arthroplasty, **32**(6), pp. 1954–1958.

[6] Andreykiv, A., Janssen, D., Nelissen, R., and Valstar, E. R., 2012, "On Stabilization of Loosened Hip Stems Via Cement Injection Into Osteolytic Cavities," Clin. Biomech., **27**(8), pp. 807–812.

[7] Malan, D. F., Valstar, E. R., and Nelissen, R., 2014, "Percutaneous Bone Cement Refixation of Aseptically Loose Hip Prostheses: The Effect of Interface Tissue Removal on Injected Cement Volumes," Skeletal Radiol., **43**(11), pp. 1537–1542.
[8] de Poorter, J. J., Obermann, W. R., Huizinga, T. W. J., and Nelissen, R., 2006, "Arthrography in Loosened Hip Prostheses. Assessment of Possibilities for Intra-Articular Therapy," Jt. Bone Spine, **73**(6), pp. 684–690.
[9] de Poorter, J. J., Hoeben, R. C., Hogendoorn, S., Mautner, V., Ellis, J., Obermann, W. R., Huizinga, T. W. J., and Nelissen, R., 2008, "Gene Therapy and Cement Injection for Restabilization of Loosened Hip Prostheses," Human Gene Ther., **19**(1), pp. 83–95.
[10] de Poorter, J. J., 2010, "Gene Therapy and Cement Injection for the Treatment of Hip Prosthesis Loosening in Elderly Patients," Ph.D. dissertation, Leiden University, Leiden, The Netherlands.
[11] de Poorter, J. J., Hoeben, R. C., Obermann, W. R., Huizinga, T. W. J., and Nelissen, R., 2008, "Gene Therapy for the Treatment of Hip Prosthesis Loosening: Adverse Events in a Phase 1 Clinical Study," Human Gene Ther., **19**(10), pp. 1029–1038.
[12] Kraaij, G., Malan, D. F., van der Heide, H. J. L., Dankelman, J., Nelissen, R. G. H. H., and Valstar, E. R., 2012, "Comparison of Ho:YAG Laser and Coblation for Interface Tissue Removal in Minimally Invasive Hip Refixation Procedures," Medical Eng. Phys., **34**, pp. 370–377.
[13] Kraaij, G., Tuijthof, G. J. M., Dankelman, J., Nelissen, R. G. H. H., and Valstar, E. R., 2015, "Waterjet Cutting of Periprosthetic Interface Tissue in Loosened Hip Prostheses: An In Vitro Feasibility Study," Med. Eng. Phys., **37**, pp. 245–250.
[14] Schmolke, S., Pude, F., Kirsch, L., Honl, M., Schwieger, K., and Kromer, S., 2004, "Temperature Measurements During Abrasive Water Jet Osteotomy," Biomed. Tech., **49**(1–2), pp. 18–21.
[15] Honl, M., Rentzsch, R., Muller, G., Brandt, C., Bluhm, A., Hille, E., Louis, H., and Morlock, M., 2000, "The Use of Water-Jetting Technology in Prostheses Revision Surgery-First Results of Parameter Studies on Bone and Bone Cement," J. Biomed. Mater. Res., Part B, **53**(6), pp. 781–790.
[16] Hloch, S., Valicek, J., and Kozak, D., 2011, "Preliminary Results of Experimental Cutting of Porcine Bones by Abrasive Waterjet," Tech. Gazette, **18**, pp. 467–470.
[17] Honl, M., Rentzsch, R., Schwieger, K., Carrero, V., Dierk, O., Dries, S., Louis, H., Pude, F., Bishop, N., Hille, E., and Morlock, M., 2003, "The Water Jet as a New Tool for Endoprosthesis Revision Surgery—An In Vitro Study on Human Bone and Bone Cement," Bio-Med. Mater. Eng., **13**, pp. 317–325.
[18] Schwieger, K., Carrero, V., Rentzsch, R., Becker, A., Bishop, N., Hille, E., Louis, H., Morlock, M., and Honl, M., 2004, "Abrasive Water Jet Cutting as a New Procedure for Cutting Cancellous Bone–In Vitro Testing in Comparison With the Oscillating Saw," J. Biomed. Mater. Res., Part B, **71**, pp. 223–228.
[19] Breusch, S. J., and Malchau, H., 2005, *The Well Cemented Total Hip Arthroplasty—Theory and Practice*, Springer-Verlag, Berlin, Heidelberg.
[20] Pitto, R. P., Koessler, M., and Kuehle, J. W., 1999, "Comparison of Fixation of the Femoral Component Without Cement and Fixation With Use of a Bone-Vacuum Cementing Technique for the Prevention of Fat Embolism During Total Hip Arthroplasty—A Prospective, Randomized Clinical Trial," J. Bone Jt. Surg. Am., **81A**, pp. 831–843.
[21] Breusch, S. J., Norman, T. L., Schneider, U., Reitzel, T., Blaha, J. D., and Lukoschek, M., 2000, "Lavage Technique in Total Hip Arthroplasty—Jet Lavage Produces Better Cement Penetration Than Syringe Lavage in the Proximal Femur," J. Arthroplasty, **15**(7), pp. 921–927.
[22] Jansson, V., 1994, "The Cement-Canal Prosthesis—A New Cementation Technique Studied in Cadaver Femora," Acta Orthop. Scand., **65**(2), pp. 221–224.
[23] Juliusson, R., Arve, J., and Ryd, L., 1994, "Cementation Pressure in Arthroplasty—In-Vitro Study of Cement Penetration Into Femoral Heads," Acta Orthop. Scand., **65**(2), pp. 131–134.
[24] Schmidutz, F., Dull, T., Voges, O., Grupp, T., Muller, P., and Jansson, V., 2012, "Secondary Cement Injection Technique Reduces Pulmonary Embolism in Total Hip Arthroplasty," Int. Orthop., **36**(8), pp. 1575–1581.
[25] Cristofolini, L., Erani, P., Grupp, T., Jansson, V., and Viceconti, M., 2007, "In Vitro Long-Term Fatigue Endurance of the Secondary 'Cement Injection Stem' Hip Prosthesis," Artif. Organs, **31**(6), pp. 441–451.
[26] Maleike, D., Nolden, M., Meinzer, H. P., and Wolf, I., 2009, "Interactive Segmentation Framework of the Medical Imaging Interaction Toolkit," Comput. Methods Programs Biomed., **96**(1), pp. 72–83.
[27] Kroh, M., Hall, R., Udomsawaengsup, S., Smith, A., Yerian, L., and Chand, B., 2008, "Endoscopic Water Jets Used to Ablate Barrett's Esophagus: Preliminary Results of a New Technique," Surg. Endoscopy Other Interven. Tech., **22**(11), pp. 2498–2502.
[28] White, F. M., 1998, *Fluid Mechanics*, McGraw-Hill Higher Education, New York.